HOUSE OF LORDS

SESSION 1998–99
2nd REPORT

SELECT COMMITTEE ON
THE EUROPEAN COMMUNITIES

# EC REGULATION OF GENETIC MODIFICATION IN AGRICULTURE

REPORT

*Ordered to be printed 15 December 1998*

LONDON: THE STATIONERY OFFICE
£10.40

HL Paper 11-I

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NOTE: (Q) refers to a question in oral evidence in the Evidence Volume;
(p) refers to a page of written evidence in the Evidence Volume.

# SECOND REPORT

15 DECEMBER 1998

By the Select Committee appointed to consider Community proposals, whether in draft or otherwise, to obtain all necessary information about them, and to make reports on those which, in the opinion of the Committee, raise important questions of policy or principle, and on other questions to which the Committee considers that the special attention of the House should be drawn.

ORDERED TO REPORT

## EC REGULATION OF GENETIC MODIFICATION IN AGRICULTURE

6378/98/98 (COM(98) 85) Proposal for a European Parliament and Council Directive amending Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms

### PART 1: INTRODUCTION

1. Genetic modification[1] (GM) is a branch of biotechnology. It involves the insertion of genes from one organism into another so as to produce a modified organism[2] (GMO) with different characteristics. Many different plants have been or could potentially be modified to change a wide range of characteristics, from herbicide tolerance and pest resistance to extended ripening or altered nutritional content. Present modifications are but the beginning of what is a technological development of great importance. There has been little progress in the genetic modification of animals[3], but experiments to modify fish for faster growth and tolerance to cold have been successful[4]. The private sector has invested heavily in the technology of genetic modification and five major agro-chemical/seed companies[5] control most of the agricultural applications world-wide.

2. Genetic modification offers great potential benefits for agriculture, industry, the environment and consumers. As well as benefits, there are serious potential hazards and risks which must be addressed by proper regulation. Since 1990, the European Community (EC) has had in place a regulatory system for the control of GMOs. This consists principally of Directive 90/219/EEC on the contained use of genetically modified micro-organisms (the "contained use Directive") and Directive 90/220/EEC on the deliberate release[6] into the environment of genetically modified organisms (the "deliberate release Directive", hereafter referred to as "the Directive")[7]. The European Commission has now proposed amendments to both Directives[8]. This report is concerned with the proposed revision of the deliberate release Directive which will have to be agreed by the Council of Ministers

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1 Also known as "genetic engineering".

2 For the purposes of the EC Directive on the deliberate release into the environment of genetically modified organisms (Directive 90/220/EEC (OJ L117 (8 May 1990) pp 15-27)), "organism" is defined as any biological entity capable of replication or of transferring genetic material; "genetically modified organism" (GMO) as an organism in which the genetic material (DNA or RNA) has been altered in a way that does not occur naturally by mating and / or natural recombination (Article 2).

3 Cloning, as with Dolly the sheep, is not strictly genetic modification as no gene has been inserted or altered.

4 European Parliament Committee on Agriculture and Rural Development, report on the impact of biotechnology on agriculture, B1. See also the Health and Safety Executive (HSE) on behalf of the Scottish Office, pp 350-1. See also paragraph 156.

5 AgrEvo, Dupont, Monsanto, Novartis and Zeneca (Q 627).

6 Article 2 of Directive 90/220/EEC defines "deliberate release" as "any intentional introduction into the environment of a GMO ... without provisions for containment such as physical [and/or] chemical ... or biological barriers used to limit their contact with the general population and the environment". Crops are thus released when planted in the open.

7 Both Directives were set out in OJ L117, 8 May 1990. They were due to be implemented in Member States by 23 October 1991. The text of the revision of 90/220/EEC proposed by the Commission was published on 26 February 1998. Any revision is not expected to be adopted until late 2000.

8 A revised contained use Directive was adopted by the Council of Ministers on 5 December 1998 (OJ L330, 5.12.98, p.1).

and the European Parliament under the co-decision procedure[9]. The changes proposed by the Commission have provided us with the opportunity to assess the working of the Community's regulatory system. We have also considered the impact of the process of regulation on Europe's scientific and agricultural competitiveness. Finally, we have considered issues related to public confidence in the technology and its regulation.

### SCOPE OF THIS REPORT

3. This report examines the regulatory system for the agricultural and food use of genetically modified organisms. Its principal focus is plants and products derived from them because the overwhelming majority of organisms modified using genetic modification have been plants. The technology is not yet sufficiently developed for it to be of commercial use in relation to animals. Additionally, animals would normally be used in containment, not released into the environment, and it is release which is the subject of the Directive. We have concerns about fish, which, in relation to their release, are a special case, and are dealt with in paragraph 156. This report is concerned with issues which arise directly from the use of GMOs and does not attempt to deal with wider concerns raised by the industrialisation of agriculture, though experience of the latter gives useful insights.

4. We are aware of the investigation into the ethical issues raised by genetically modified crops by a working party of the Nuffield Council on Bioethics. We had a valuable meeting with the members of the working party, but we have deliberately limited our inquiry to the efficiency and effectiveness of the EC regulatory structures.

5. This report does not consider any of the issues relating to the patenting of living systems. Some of the pertinent issues have been addressed in our report on "Patent protection for biotechnological inventions"[10]. We have also not considered the issues surrounding liability either for GM crop failure or for any damage GM crops might cause to the environment or health.

### STRUCTURE OF THIS REPORT

6. Part 2 of this report gives a detailed background covering both the technology of genetic modification and the existing regulatory system. If further background is required, the May 1998 Parliamentary Office of Science and Technology (POST) report on "*Genetically modified foods: benefits and risks, regulation and public acceptance*" can be recommended. Part 3 contains the views of witnesses, together with the Committee's opinion on the potential benefits that the technology offers and also the potential risks. We consider how the risks can be assessed and managed as well as the questions of public acceptance of the technology and the effects of regulation. The committee's opinions are presented in **bold print**. A summary of the conclusions is presented in part 4. Appendix 1 contains the membership of Sub-Committee D which conducted this inquiry and Appendix 2 is a list of witnesses, to all of whom we express our gratitude. A glossary is to be found in Appendix 3.

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9 The Environment Committee of the European Parliament has yet to report on the proposed revision of the Directive, but has received a report from a consultant (Dr von Schomberg, "*An appraisal of the working in practice of Directive 90/220/EEC on the deliberate release of genetically modified organisms*" Final Study, European Parliament Scientific and Technological Options Assessment, (STOA), January 1998, PE 166.953/Final. (For Dr von Schomberg's evidence, see pp 401-2.)) The committee had not reported when this report was ordered to be printed. The Economic and Social Committee of the European Community has volunteered an opinion on the role of GM within agriculture ("Genetically modified organisms in agriculture - impact on the Common Agricultural Policy", July 1998) and has also produced a report on the revision of the Directive (CES 1117/98, 9-10 September 1998).

10 European Communities Committee, 4th Report (1993-94), HL 28.

## PART 2: BACKGROUND

### WHAT IS GENETIC MODIFICATION?

*Definitions*

7. The Convention on Biological Diversity[11] defines biotechnology as "any technological application that uses biological systems, living organisms or derivatives thereof to make or modify products or processes for specific use". Biotechnology has been employed for millennia: fermentation, bread-making, brewing and cheese-making were developed by the Egyptians from about 2000 BC. A definition of modern biotechnology, which is developing new techniques all the time, is difficult, but current use implies the introduction of hereditary material which could not have been achieved using traditional breeding methods[12]. The United Nations Environmental Programme guidelines for safety in biotechnology[13] define genetic modification as "modern biotechnology used to alter genetic material of living cells or organisms in order to make them capable of producing new substances or performing new functions".

*DNA and genes*

8. The complete set of instructions for making any living organism, from the simplest bacteria to human beings, is called a genome. This contains the master blueprint for all cellular structures and activities for the lifetime of the cell or organism. It is encoded within a set of molecules called DNA (or RNA for some viruses)[14]. Each DNA molecule contains many genes which are the basic physical and functional units of heredity. Genes are "units" of DNA coding for a single product (nearly always a protein). There is a universal genetic code which applies from the simplest organisms to human beings[15]. The code allows a stretch of DNA to specify the structure of a particular protein. The amount of protein produced may vary depending on cell type, timing, environmental stress and a variety of other effects. A gene is "expressed" when the protein is synthesised[16]. Although most cells in the organism will contain the gene, the degree of expression may vary from cell to cell and tissue to tissue and thus the amount of the protein will similarly differ greatly.

9. A crop-plant genome contains approximately 50,000 genes[17], but only about 10 per cent. of the DNA is used for coding genes. The rest includes control sequences that identify when and where particular genes are expressed in the organism and regions whose function is unknown[18]. The DNA is largely conserved during the lifetime of an organism, but is redistributed when eggs, sperm or their equivalents are formed. It is only in a clone that DNA is conserved unchanged between generations. Genes, whether introduced using genetic modification or inherently present in an organism, may be unstable, may interact with other genes and are capable of movement within the genome. In addition, their expression may be influenced by the environment.

*Inserting genes*

10. Most organisms are only sexually compatible within their own species, and genes cannot normally be transferred from one species to another. Genetic modification allows the identification of individual genes which can then be decoded, manipulated, copied and transferred into any other

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[11] The Convention on Biological Diversity (Rio de Janeiro, 1992) (Cm 2127) is a binding agreement signed by over 170 countries (though not ratified by the United States). It came into force on 29 December 1993 (DETR pp 190-1).

[12] This would not include gene deletion or movement of genes within the genome, as these are possible naturally (Gene deletion does not require the deletion of an entire gene. The change or loss of a single unit in the DNA sequence may result in the absence of the gene product, effectively deletion.).

[13] United Nations Environmental Programme International Technical Guidelines for Safety in Biotechnology, 1996. These Guidelines arose from the requirement in Chapter 16 of Agenda 21 (adopted at the United Nations Conference on Environment and Development in Rio de Janeiro in 1992) for the "Environmentally Sound Management of Biotechnology" and were first developed by the United Kingdom and the Netherlands.

[14] Deoxyribonucleic acid (DNA) and Ribonucleic acid (RNA).

[15] Due to this commonality, the transfer of genes from animals to plants is thus not that remarkable (Professor Bainbridge, of the University of Teesside and chairman of the advisory committee on novel foods and processes, Q 682).

[16] I.e. when the cell makes the protein.

[17] The human genome is thought to contain between 60,000-70,000 genes and a similar percentage of the DNA is used for coding genes.

[18] Possibly in reserve for future use.

organisms. In most instances the genes are transferred along with the instructions (termed "promoters") as to when in time and in what tissue they might be expressed. The techniques of genetic modification allow the transfer of genes from any organism to cells of virtually any other (using appropriate techniques) thus removing the species barrier. Genes can thus be transferred between bacteria, plants and animals (see paragraph 110). For plants and animals this is complicated by the need to introduce the genes into all the cells in the organism. Although the introduction of genes into plant cells is more difficult than it is into animal cells, the ability to regenerate many complete plants from a single cell makes plant biotechnology much easier.

11. The proportion of the genome of the host organism that is modified is currently very small: two or three genes and their associated control elements amongst tens of thousands. The precise sequence of the genes intended to be introduced is known. The position of insertion of the inserted genes ("transgenes"[19]) is, however, not generally known. The number of copies of the insert introduced into the genome cannot currently be controlled during the insertion process. There may be other genes (or partial genes) introduced as a consequence of the technique used, but their sequence and function is known. The introduction of copies of the transgene may disrupt genes in the host genome. If the disrupted genes are essential ones, the organism may not be able to grow, and so no organism will result. If they are relatively unimportant (such as modification of colour) the unexpected modification may become apparent during the regeneration of the entire organism. Disrupted genes which are involved in processes that are only switched on during environmental stress[20] or which are expressed only under certain conditions in the lifetime of the organism may not initially be identified. The disruption may extend to changes in the timing of expression of a gene product. These changes should however surface in the process of regenerating the plant, or during the extensive breeding and selection processes used to produce a commercially useful product.

*Methods of transferring genes*

12. There are two main methods for the transfer of genes into plants. The first involves the use of a soil bacterium, *Agrobacterium tumifaciens*, which infects certain plants. It injects a piece of DNA into the plant cell to attempt to take over the cell's protein manufacturing machinery and so produce a sugar on which the bacterium can feed. This piece of DNA is incorporated into the genome of the infected cell. Scientists use this piece of DNA by effectively hijacking it. Having removed some of the unneeded genes, they are able to insert desired genes into the vacated space. Using *Agrobacterium* it is possible to modify many dicotyledonous (broad leaf) plants such as potato, rape, tobacco and tomato and the technique has been adapted to work on maize, wheat and rice. The second method involves the use of "biolistics" (the "gene gun") where the desired gene package is coated around finely divided gold particles and literally fired into plant cells. A small percentage of the plant cells is transformed[21] in each case. In either method, one of the genes inserted into the plant will produce a protein that confers tolerance to a chemical that would normally kill the cell, a herbicide for example. When the chemical is administered, only those cells which have been effectively transformed and satisfactorily express the new gene product are not killed and a complete plant may be regenerated from these[22]. (This gene is termed a "marker gene" because it is used to identify the presence of the transgene.) The laboratory modification is only carried out on a suitable sub-set of varieties of the crop. These varieties are then crossed (and back-crossed) using traditional breeding technology in order to put the desired genetic material into choice varieties for agricultural production. These techniques are continuously being refined to make them more efficient and predictable.

13. Other methods for inserting genes are now under development. One method involves using a modified plant virus to transfer the genetic material. Deleterious genes normally found in the virus are removed and genes specifying the required characteristics inserted. The subject plant, while growing, can be inoculated with the modified virus and, in a few weeks, the virus will express the desired protein in all parts of the plant.

14. The transformation of animals is much harder, primarily because technology does not yet exist allowing the regeneration of an animal from a single cell or group of cells. The technique currently used for the modification of animals is the micro-injection[23] of DNA into embryonic cells.

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[19] The inserted genes are termed "transgenes" to differentiate them from indigenous genes.

[20] "Secondary metabolism".

[21] A transformed plant is a plant which has successfully been modified.

[22] These processes are described in greater detail in the Parliamentary Office of Science and Technology (POST) report on *"Genetically Modified Foods: benefits and risks, regulation and public acceptance"*, May 1998, especially pp 3-6.

[23] A process whereby DNA is injected directly into the cell or nucleus. In some cases this DNA is incorporated into the genome of the cell and is inherited by daughter cells.

This provides a mosaic where only some of the cells in the resulting organism are modified and others are not, but it does provide a high yield of transformed animals (described as "chimeras" as they are only partially modified). This technique is thus not of use for the modification of agricultural animals, but could be of considerable benefit in medicine, for example in the treatment of cystic fibrosis.

*What foods can be modified?*

15. All foods are of animal, plant or micro-organism origin and are therefore susceptible to modern biotechnology. Many foods are the product of traditional biotechnology, which uses micro-organisms to modify the starting material to improve taste, texture, palatability, keeping quality or safety[24]. One of the earliest modern genetic modifications enabled the production of "vegetarian cheese". The production of hard cheese used to be dependent on small quantities of rennet, scraped from the lining of dead calves' stomachs. The enzyme Chymosin is identical to rennet and is produced by genetically modified yeasts or bacteria[25]. It was introduced in commercial cheese-making in 1991 and is now used to manufacture 90 per cent. of hard cheeses (United Biscuits Q 568).

*Cost of development*

16. The technology involved in genetically modifying an organism is relatively simple and inexpensive when compared to the costs of many other new technologies. Genetic modification requires a broad research and knowledge base in biology, breeding, agronomy, physiology, biochemistry and genetics. The development process from concept to commercial crop is however exceedingly expensive and takes many years.

GENETIC MODIFICATION AND TRADITIONAL BREEDING

*Why select?*

17. All current crop plants (and all domestic animals) are the result of careful selection and breeding over centuries. Selection in the case of plants has been made on the basis of taste, colour, smell, keeping qualities, nutritional value, yield and resistance to disease. The modern crops used in our fields are in most cases utterly different from the original plants from which they have been bred[26]. Most of the food we eat results from crops for which the species of origin is not native to the country in which it is grown. In Europe, more than 90 per cent. of crop plants fall into this category. Modern plant breeding has been remarkably successful in helping to raise yields, improve quality and improve resistance to pests and diseases. New cultivars are used for many reasons, including consumer demand and security of supply. It is claimed that these choices often result in a significant loss of biodiversity amongst agricultural crop varieties.

*Traditional breeding technology*

18. Traditional breeding has the same aims as genetic modification (yield, pest or disease control, hardiness and value) and much of the process is similar. Plants can be grown or stored and regenerated from single cells. The technology used is also advanced, as for example with embryo rescue[27]. It is important to remember that traditional breeding also relies on genetic transfer, but the random transfer of tens of thousands of genes at once rather than the insertion of two or three known genes, which is genetic modification. Those tens of thousands of genes often produce undesirable traits[28] that must similarly be identified and rejected. Cloning (in the form of vegetative cuttings) has been employed by plant breeders for generations.

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[24] For example, centuries ago, fermented drinks (like beer) arguably became commonplace as water was not safe to drink. Contaminated beer could be recognised far more easily than contaminated water.

[25] A variety of Chymosin producing systems were permitted by ACNFP in 1991. The first vegetarian cheese was put on sale in 1992.

[26] All modern crop plants bear little relation to their ancestral precursors. For example, today's wheats bear no visible relation to their bushy Egyptian ancestors as the crop has been bred continuously to achieve desired qualities.

[27] The Royal Society's recent statement on "Genetically modified plants for food use" (September 1998) highlights this technique, used, for example, in sunflower breeding. If crosses are performed between sunflowers that have greatly differing genetic make-ups, the pollen will fertilise the receiving plant but the resulting embryo will abort before a seed is produced. In embryo rescue, the embryo is removed before abortion occurs and grown outside the parent plant to produce a new plant to enable crosses to be made between sunflower species which would not normally be sexually compatible.

[28] Many plants contain genes which, if expressed, would produce undesirable toxins. For example, the DNA of the potato is very similar to that of deadly nightshade, but the problematic genes are not expressed.

*Subsequent selection*

19. The genetic modification of plants is only an initial step in the production of a commercial plant variety. With both traditionally and modern genetically modified plants, the new plants are grown through a number of generations (over several years) in order to identify those that have been successfully modified and separate out those in which any unwanted changes have occurred. In most instances this process will identify any of the deleterious effects identified in paragraph 11. Traditional breeding methods are then used to ensure that the plant variety is "distinct, uniform and stable"[29] and the initially transformed plant may be crossed with many other varieties for agricultural and economic reasons[30].

*Similar risks?*

20. The risks involved in using genetic modification are discussed in greater detail in part 3, but it should be noted here that, whatever the method of production, the quest for novel traits produces similar risks. For example, when stress tolerances[31] are altered, the risks resulting from indirect effects caused by changes in land use are potentially significant. The consequences of introducing novel species into a new environment, on their own or for breeding, can be extremely damaging[32]. Each plant introduced from a foreign country brings with it tens of thousands of genes previously unknown in the United Kingdom. Risk is particular to an ecosystem and traditionally bred crops with novel traits and weedy relatives where they are to be released may present a greater problem, in relation to out-crossing, than genetically modified crops released where they have no such relatives.

21. While there is great similarity and overlap between the new and traditional techniques, genetic modification is also a departure as it permits the production of that which cannot be created by traditional breeding. The barriers of sexual compatibility are broken. Traits are given to a crop which it could not have acquired by any other means and from this arise new, predominantly environmental, issues. The technology allows the aims of traditional breeding to be achieved faster and with far greater accuracy and precision: only the necessary number of genes (at present in single figures) whose behaviour is known is transferred, as opposed to the essentially random process of traditional breeding with the involvement of tens of thousands of genes.

KEY EVENTS

22. Biotechnology was probably first used by the Egyptians from 2000 BC, when they developed techniques such as fermentation (see paragraph 7). It was Gregor Mendel (1822–1884) who first described the particulate nature of inheritance[33] that we now describe as genes. William Bateson[34] coined the word genetics in 1905 and Wilhelm Johannsen attached the name "genes" to the Mendelian units of heredity in 1909. In 1903 Walter Sutton recognised the chromosomes as the carriers of Mendel's units of heredity[35], but it was only in 1944 that Avery, MacLeod and McCarty identified DNA as the "genetic material". The real breakthrough in modern molecular biology was the Cambridge elucidation of the structure of DNA in 1953 by Watson and Crick. Two chains, complementary to one another, built into the molecule were discovered to be the key to heredity. The following half century has seen a revolution in our understanding of the manner in which genetic information is expressed within cells and passed between cells and generations. It is only now, after this half a century of learning, that commercial applications of these discoveries are appearing. While the early products of genetic modification (such as human insulin) were in use from the early 1980s, the first release of a GMO into the environment of the United Kingdom was not until 1986[36]. The first GMO which could have been used in food, a modified yeast for bread, was approved in 1990 and the first plant (a delayed ripening tomato) in 1995, but while this product may be imported into Europe

[29] Under Article 6 of Council Regulation (EC) No. 2100/94 of 27 July 1994 on Community Plant Variety Rights (OJ L227, 1 September 1994, pp 1-30), Community plant variety rights shall only be granted for varieties that are "distinct, uniform, stable and new". A similar requirement is contained in section 4 of the Plant Varieties and Seeds Act 1997.

[30] It is estimated that there are about two hundred varieties of soya modified to be tolerant to glyphosate on the market in the United States (American Soybean Association, p 295).

[31] See paragraph 82.

[32] For example, the consequences of the introduction to the United Kingdom of the varroa mite has been devastating for bee keepers.

[33] That characteristics, rather than parts of characteristics, are inherited from each parent.

[34] The first Director of the John Innes Institute.

[35] T.H. Sutton, "The chromosomes in heredity", 1903, Biological Bulletin 4, pp 231-251.

[36] An oilseed rape.

and used for food it still awaits approval to be grown within the Community. As well as developing and regulating the science, the United Kingdom has also explored the ethics of genetic modification through the reports of the Polkinghorne[37] and Banner[38] committees.

23. Currently, no GM crop is being grown on a commercial scale in the EC, though some permits have been issued and many applications are in progress (see Appendix 4). Permits exist for a variety of maize produced by Novartis to be grown commercially[39] and to be used for animal feed. It is this particular variety which is the subject of a lawsuit in France, the Member State which issued the marketing consent at the successful conclusion of the EC process. In February 1998 Greenpeace applied to the French courts to overturn the issuing of the consent. The Conseil d'etat issued an injunction preventing the marketing of the maize until the case put by Greenpeace had been resolved. GM tomatoes are on trial in Spain, but a commercial permit has not yet been issued. Chymosin (used in vegetarian cheese) is an enzyme and is produced in laboratories, a release permit is not thus required.

24. GM varieties of maize and soya, two major commodity crops, are being grown on an increasingly large scale in north America. These varieties have been modified for herbicide tolerance, insect resistance or both. GM tomatoes are also being grown. The crops which are imported into the EC have all had to be approved for the uses (food or animal feed), to which they are put. The tomatoes have been approved for use as paste; soya and its derivatives for food use and maize for use as an animal feed. If the crop has been sufficiently processed to mean that it poses no environmental risk, a release permit is not required for import[40].

25. Varieties of GM soya and maize have not been segregated from their unmodified equivalents and are thus entering Europe in "co-mingled" shipments (see paragraphs 129–134).

## HISTORY OF REGULATION

### *The Ashby report*

26. Regulation of biotechnology was first considered in the early 1970s when the scientists at the forefront of the technology called for and achieved a voluntary moratorium until a number of safety questions had been addressed. The United Kingdom was one of the first countries to develop a regulatory strategy. In 1975 a working party chaired by Lord Ashby[41] recommended that genetic manipulation techniques should be allowed to proceed but with rigorous safeguards. They believed that the technology would provide "substantial (though unpredictable) benefits" leading to a rapid advance in our detailed understanding of gene action: "...application of the techniques might enable agricultural scientists to extend the climatic range of crops and to equip plants to secure their nitrogen supply from the air." They concluded that "it is not inconceivable that the technique might ultimately lead to ways to cure some human diseases known to be due to genetic deficiency."[42] At the time it was only possible to modify micro-organisms in the laboratory. The hazards were thus seen to be of two forms, those that might affect the research workers and those that might affect the public at large. The report recommended containment and precautionary measures to protect those working in the laboratories and believed that the barriers thus created would be sufficient to protect the general public. The general environment, including plants and animals, was not considered at that time[43].

### *Development of United Kingdom regulations*

27. The Genetic Manipulation Advisory Group (GMAG) was set up in 1976 to examine proposals for genetic manipulation. The Health and Safety (Genetic Manipulation) Regulations 1978 required any activity involving genetic manipulation to be notified to GMAG and the Health and Safety Executive (HSE). In 1984 GMAG was replaced by the Advisory Committee on Genetic Modification

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37 Report of the committee on the ethics of genetic modification and food use, HMSO 1993.

38 Report of the committee to consider the ethical implications of emerging technologies in the breeding of farm animals, HMSO 1995.

39 The application was the subject of controversy as the maize contains an ampicillin resistance gene (see paragraph 75).

40 Thus soya beans require a release permit but soya flour or oil does not. Tomatoes do but tomato paste does not if it contains no viable seeds.

41 Report of the Working Party on the Experimental Manipulation of the Genetic Composition of Micro-organisms, January 1975, Cmnd. 5880.

42 Ibid., para. 6.1.

43 The general environment was not considered until 1989.

(ACGM) which still advises the Health & Safety Executive on the contained use of genetically modified organisms[44]. ACGM's remit is the safety of genetic modification used in containment; it does not consider ethical or social issues[45]. This remit extended initially only to the protection of human health and safety. However, formal guidelines issued by ACGM[46] did include a requirement to provide the HSE with an assessment of the environmental consequences of an intentional release of a genetically modified organism into the environment.

28. The first piece of primary legislation in the United Kingdom dealing specifically with GMOs and the environment was Part VI of the Environmental Protection Act 1990. It established a structured regime of risk assessment and notification with the aim of preventing or minimising "any damage to the environment which may arise from the escape or release from human control of GMOs"[47]. The Act also provided for a system of consents to import, acquire, release or market GMOs. At the same time as this legislation was passing through Parliament, the European Commission was developing EC proposals on the control of GMOs. These resulted, in April 1990, in the two Directives on contained use and deliberate release (see paragraphs 2, 29–30 and 32–36). The Directives have provided the basis for subsequent United Kingdom legislation regulating the use of GMOs.

*Safety in containment*

29. The EC's contained use Directive (90/219/EEC)[48] covers only genetically modified micro-organisms. It has been implemented in the United Kingdom by the GMO (Contained Use) Regulations 1992[49]. The aim of the United Kingdom Regulations is the protection of "persons against risks to their health, whether immediate or delayed, and the protection of the environment"[50]. Although the scope of these Regulations is wider than the EC Directive, extending to activities involving any GMOs (including both animal and plant cell cultures), the provisions relating to the protection of the environment only apply to genetically modified micro-organisms[51]. The Regulations are thus, as regards environmental protection, co-extensive with the EC Directive. For larger genetically modified organisms, such as plants and animals, the regulations only cover risks to human health. The environmental risks associated with work with larger organisms are covered separately by section 108(1)(a) of the Environmental Protection Act 1990, which requires an assessment of environmental risks. There are specific regulations[52] for these larger organisms that require records on the risk assessment to be kept for 10 years, but details of the risk assessment are not notified to Government.

30. The main requirements of the control regime established by the Contained Use Regulations are: to carry out a prior assessment of the risks to human health and the environment arising from any activity involving genetic modification and to maintain records thereof; to notify the HSE of an intention to use premises for the first time for genetic modification (and for some activities to wait for consent from HSE before work may start); and to notify the HSE of individual activities involving genetic modification, which for some activities may involve waiting for a consent before proceeding. There is a provision enabling the HSE to accept as a single notification "a connected programme of work covering more than one activity involving genetic modification at one site, or a single activity carried on by the same person at more than one site"[53]. Once an intention to use premises for the first time for activities involving genetic modification has been notified to the HSE, there is no further requirement for a separate notification in respect of activities on those premises involving so-called Group 1 micro-organisms: those which are unlikely to cause disease to humans, animals or plants or to cause adverse effects in the environment. Most animals and plants are classed as Group 1 organisms. Thus a controversial experiment need not be notified to the regulators if an uncontroversial experiment has previously been conducted on the same site. The regulations do however provide for a separate

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44 Health and Safety Executive, p 348.

45 Ibid.

46 Given statutory force in the Genetic Manipulation Regulations 1989, SI 1989/1810 which superseded and revoked the 1978 Regulations.

47 Section 106(1).

48 OJ L117 (8 May 1990) pp 1-14.

49 SI 1992/3217 as subsequently amended by SI 1993/15, SI 1996/967 and SI 1996/1106.

50 Reg 3(1).

51 Reg 3(4).

52 SI 1996/1106 (which completely replaced SI 1993/15) and SI 1997/1900.

53 Reg 9(7).

notification if there is "a significant change in any premises or activity" after the initial notification, or if any new information comes to light which could affect the particulars previously notified[54].

*Release into the environment*

31. Initially ACGM considered the safety of all uses of transgenic organisms, either by regulation (for contained use) or through a voluntary code of practice (for intentional introductions to the environment). Its formal remit was to consider only human health and safety, as containment assumed neither escape nor release. The committee did, however, evaluate the first deliberate releases and considered their probable impact on the environment.

32. Part VI of the Environmental Protection Act 1990 provided the first specific regulation to prevent or minimise the damage to the environment from GMOs. The Act required a risk assessment to be made and submitted to the Department of the Environment. In certain cases a consent had to be obtained and the Advisory Committee on Releases into the Environment (ACRE) was established to advise the Secretary of State responsible for the environment on such matters. Thus the United Kingdom, unlike most other countries, had by 1990 evolved its own broad regulatory structure[55] and system of scientific advisory committees. This system has been copied by many countries, including those as far afield as Brazil, Russia and South Africa.

33. At the same time, the Commission was preparing Community legislation. The deliberate release Directive has been implemented in the United Kingdom by the GMO (Deliberate Release) Regulations 1992[56]. The 1992 Regulations and the substantive provisions of the Environmental Protection Act 1990 came into force in the United Kingdom on 1 February 1993.

34. The deliberate release Directive and the United Kingdom Regulations both apply to the release into the environment of all GMOs (as defined), whether micro-organisms or not. Their principal objective is to prevent or minimise any damage to the environment, defined as "the presence in the environment of GMOs which have (or of a single such organism which had) escaped or been released from a person's control and are (or is) capable of causing harm to the living organisms supported by the environment"[57]. "Harm" means "harm to the health of humans or other living organisms or other interference with the ecological systems of which they form part and, in the case of man, includes offence caused to any of his senses or harm to his property"[58]. The key test of harmfulness in relation to GMOs is based on their potential, rather than actual or proven, effects[59]. Controls on the deliberate release and marketing of GMOs are based on a general prohibition, followed by procedures for obtaining prior consent to releases. The Regulations prescribe the information to be contained in an application for consent to release GMOs, which has to be accompanied by a "statement evaluating the impacts and risks posed to human health and the environment"[60]. In the case of applications for consent to market a genetically modified product, "an assessment of any risks for human health or the environment related to the GMOs contained in the product, including information obtained from the R&D stage on the impact of the release on the environment", is required[61].

## REGULATION AT PRESENT

*Environmental safety*

35. The competence of the European Community to legislate on biotechnological matters is based on a number of Treaty provisions covering the environment, health and safety of workers, and the approximation of laws to establish an internal market. There are, in addition, regulations in place that apply to the agricultural use of all products, whether genetically modified or not. Micro-organisms modified in the research or development laboratory are subject to regulation under the terms of the

54 Reg 10(4).

55 Science and Technology Committee, 7th Report (1992-93), *Regulation of the United Kingdom Biotechnology Industry and Global Competitiveness* (HL 80), para. 4.3.

56 SI 1992/3280, as amended by SI 1993/152, SI 1995/304 and SI 1997/1900.

57 Environmental Protection Act 1990, section 107(3).

58 Ibid., section 107(6).

59 Ibid., section 107(7).

60 Reg 6(1).

61 Reg 11(2)(b).

contained use Directive (90/219/EEC)[62] and the Biological Agents at Work Directive (90/679/EEC)[63]. The latter applies only to micro-organisms, but the definition includes animal and plant cells in tissue culture. There are specific United Kingdom regulations governing the use and treatment of animals.

36. If there is an expectation that the organisms may be deliberately released[64] into the environment, Part B of the deliberate release Directive (90/220/EEC)[65] imposes a notification requirement and specifies the information which must be provided to the competent national authorities. This comprises a technical dossier and an evaluation of the impact and risks to human health or the environment[66]. Part C of the Directive establishes a Community procedure for authorising consents for marketing genetically modified organisms (whether released into the environment or not). This includes a requirement for an environmental risk assessment, except if such or a similar assessment is mandatory in respect of products covered by other EC legislation[67]. The Commission's proposed revision of Directive 90/220/EEC was published on 26 February 1998, and it is on this text that we base our specific comments on the reform of the regulatory system.

*Food safety*

37. Specific legislation exists for novel foods and food ingredients and also for products intended for use as drugs for human or animal use[68]. On 15 May 1997 the European Community's Novel Foods Regulation came into effect and introduced a mandatory pre-market approval system for novel foods throughout the Community[69], substantially based on the approach developed by the United Kingdom[70]. In the United Kingdom, the Advisory Committee on Novel Foods and Processes (ACNFP), established in 1988, advises the Minister of Agriculture, Fisheries and Food and the Secretary of State for Health on applications. The scope of the Regulation includes foods and food ingredients derived from genetically modified organisms and has been supplemented by Council Regulation (EC) 1139/98[71] which requires foods derived from genetically modified soya and maize to be labelled as genetically modified, from 1 September 1998, if either protein or DNA resulting from genetic modification is present.

*Intellectual property*

38. The final adoption of Directive 98/44/EEC[72] in July 1998 on the legal protection of biotechnological inventions follows years of debate about patenting living organisms. The Directive will have to be implemented by Member States no later than 30 July 2000. One aim of the Directive is to harmonise the legal protection of biotechnological inventions between Member States, so as to remove any possible barriers to trade created by different laws and practices in the Member States. It may have a significant effect on the application of biotechnology in agriculture as it clarifies the distinction between plant variety registration and patents in relation to genetically modified plants[73]. It prohibits the patenting of processes that modify the genetic identity of animals, and which are likely to

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62 90/219/EEC on the contained use of genetically modified micro-organisms (OJ L117 (8 May 1990) pp 1-14). A revised contained use Directive was adopted by the Council of Ministers on 5 December 1998 (OJ L330, 5.12.98, p.1).

63 90/679/EEC on the protection of workers from risks related to exposure to biological agents at work (OJ L374 (31 December 1990) pp 1-12). This Directive (which includes genetically modified micro-organisms) is implemented in the United Kingdom within the Control of Substances Hazardous to Health (COSHH) Regulations.

64 See footnote 6.

65 Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms (OJ L117 (8 May 1990) pp 15-27). The Directive was first implemented in 1990. The text of the proposed revision is COM(98) 85 final, published 26 February 1998.

66 90/220/EEC Article 5(2)(b).

67 90/220/EEC Article 10(2).

68 Medicines Act 1968 and 1971 and EC Regulation No. 209/93 (OJ L25 (2 February 1993) p 18) for human and veterinary medicines; Food and Environment Protection Act 1985 for pesticides.

69 Novel Foods and Novel Food Ingredients Regulation, No. 258/97 (OJ L43 (14 February 1997) pp 1-7). The Regulation is described in detail in the Report for 1997 of the Advisory Committee on Novel Foods and Processes.

70 Professor Bainbridge, Q 673.

71 Concerning the compulsory indication of the labelling of certain foodstuffs produced from genetically modified organisms (OJ L159 (3 June 1998) pp 4-7).

72 OJ L213 (30 July 1998) pp 13-21.

73 Directive 98/44/EEC (OJ L213 (30 July 1998) pp 13-21), preamble paras 29 –33, where an attempt is made to distinguish between the production of a new plant variety and the insertion of a transgene into a 'plant grouping'.

cause them suffering without any substantial medical benefit to man or animal[74]. While also prohibiting the patenting of plant and animal varieties, the Directive provides that "Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety."[75]

## PRINCIPLES OF REGULATION

### *Why GM-specific regulation?*

39. Any specific regulation of biotechnology relies on the assumption that there is risk that is in some sense different from the risks that attend similar products. In 1986 the OECD group of national experts on safety in biotechnology recommended "that there is no scientific basis for specific legislation to regulate the use of recombinant DNA organisms"[76]. This recommendation depended on there being in place legislation capable of being used to ensure the safe handling of these organisms. The primary reason for the introduction of specific legislation in Europe was seen to be the need for provision of a "harmonised regulatory framework" and "to provide for the protection of human health and the environment"[77].

### *Risk: from means or end?*

40. Risks arise not from the technology used to create a new organism but rather from the characteristics of the new organism itself. This includes the properties of the introduced genetic material and the organism's interaction with the environment. It is arguable that legislation that addressed all the implications of the introduction or use of novel organisms for human and animal health and safety and for the environment would have been preferable to a system for which the trigger is the use of particular techniques. The alternative to the introduction of specific legislation in 1990 would have been the harmonisation of all law applicable to the protection of human health and the environment. The Commission recognised that this was not practicable in one step, but it also envisaged that the scope of application of the EC Directives on GMOs would gradually be reduced as new product-specific legislation was adopted. Products covered by other EC legislation are exempted from certain provisions of the deliberate release Directive[78] concerning environmental risk assessment. Moreover, the Commission has given an undertaking that "when preparing legislation on marketing authorisation for products consisting of, containing or which could contain GMOs, to include in its proposals provisions for a specific environmental risk assessment of the product similar to that provided in this Directive. The Commission also undertakes, where appropriate, to propose modifications to existing product legislation in order to provide for such environmental risk assessment."[79]

### *The precautionary principle*

41. Article 130r(2) of the EC Treaty states that "Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall be based on the precautionary principle and on the principles that preventative action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay. Environmental protection requirements must be integrated into the definition and implementation of other Community policies". The 1992 Rio declaration on environment and development (Principle 15) states: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

42. This precautionary principle is reflected in the EC directives on genetically modified organisms. It has been asserted that the deliberate release Directive 90/220/EEC "is the first piece of

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[74] Ibid., preamble para. 45 and Article 6(2)(d).

[75] Ibid., Article 4(2).

[76] Recommendation of the Council of the OECD, 16 July 1986 and Mr Cantley, of the OECD, p 300.

[77] Explanatory Notes on 90/219/EEC (XI/596/91-Rev. 1 and the Explanatory Notes on 90/220/EEC (XI/401/91-Rev. 2), explaining the reasoning behind Article 1 of the Directives. See also Mr Cantley, p 301.

[78] Article 10(2).

[79] 90/220/EEC, Article 10 and Commission Declaration in the Minutes of the Council Meeting of 23 April 1990 (see Mr Cantley, p 301).

international legislation in which the precautionary principle is translated into precautionary regulation"[80]. The preamble to the Directive identifies the necessity for "harmonised procedures and criteria for the case-by case evaluation of the potential risks arising from the deliberate release of GMOs into the environment". It also states that the introduction of GMOs into the environment should be carried out according to the 'step-by-step' principle. Under this principle "the containment of GMOs is reduced and the scale of release increased gradually, step by step, but only if evaluation of the earlier steps in terms of protection of human health and the environment indicates that the next step can be taken."[81]

### Principles of risk assessment and risk management

43. Risk assessment is the scientifically-based process which attempts to identify and characterise hazards[82], and the likelihood of hazard occurring, risk[83]. It deals with the probability of an event causing a potentially undesirable effect. It attempts to be quantitative, and one of the criticisms of the approach taken in managing the risk for the release of genetically modified organisms is that the assessment is qualitative[84] only. Dr Gliddon, of the University of Wales, identified a structure for risk assessment and suggested that risk assessment was feasible even where knowledge was limited. It involved the identification of hazards; estimation of their magnitude; estimation of the frequency of their occurrence; and evaluation of the risks[85]. Risk is never zero, but it can be minimised by taking appropriate precautions (risk management); for example, to limit exposure to a harmful substance or situation[86]. "The goal of risk management is scientifically sound, cost-effective, integrated actions that reduce or prevent risks while taking into account social, cultural, ethical, political and legal considerations"[87]. The United States Presidential/Congressional Commission on risk assessment and risk management[88] recommended that the process of risk management should include the following: define the problem and put it in context; analyse the risks associated with the problem in context; examine options for addressing the risks; make decisions about which options to implement; take actions to implement the decisions; and conduct an evaluation of the actions' results. This procedure should be used in collaboration with stakeholders and repeated if new information arises that changes the need for or nature of risk management.

### Differences between the US and EC regulatory approaches

44. The United States is the major user of commercial applications of modern biotechnology[89] with 27.8 million hectares of genetically modified crops under cultivation in 1998[90]. It is also the largest commodity crop exporter. The United States has regulated biotechnology in a very different manner to the approach taken in Europe. While the regulators in both systems ask similar questions, the United States takes an optimistic approach ("Why not?")[91] whereas Europe is more pessimistic and involves predicting the unexpected ("Why?").

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80 Dr von Schomberg, author of a report to the European Parliament on the working of 90/220/EEC (see footnote 9), pp 401-2.

81 90/220/EEC, OJ L117 (8 May 1990) p15.

82 Hazard is defined as the situation that in particular circumstances could lead to harm. This is taken from the 1992 report of the Royal Society: "*Risk: analysis, perception and management*"; a definition accepted by the Science and Technology Committee in their report on biotechnology (7th Report (1992-93, HL 80, para. 5.26).

83 Risk is defined as the probability that a particular adverse effect occurs within a stated period of time or results from a particular challenge. Sources as previous footnote.

84 Quantitative: nine out of ten cats prefer smoked salmon. Qualitative: cats prefer smoked salmon.

85 Dr Gliddon, p 340.

86 In American usage, until the Presidential / Congressional report, risk assessment was the component of the overall process devoted to the calculation of risk and risk analysis was the overall process including risk assessment. In Europe (as in Australia) risk assessment is understood to be the overall process, c.f. T. Beer: "*Environmental Risk Assessment: an Australian perspective*", 1995.

87 Presidential/Congressional Commission on Risk Assessment and Risk Management: "*Framework for Environmental Health Risk Management*", January 1997, p 1.

88 Ibid.

89 Though figures are not available for China.

90 Of which 71 per cent. was herbicide tolerant (*New Scientist*, 31 October 1998 (No 2158), p 46).

91 Professor Beringer, Q 21.

45. Unlike the European Community, the United States government decided that existing laws could be used to ensure the safe use of genetically modified organisms[92]. "The United States believes that the new techniques of genetic engineering are an extension of biotechnology in general and, thus, new products developed through these techniques are extensions of existing product classes."[93] The United States' process has operated more efficiently than that in the EC as the Community has to reconcile 15 different Member States' approaches to the technology and 15 different regulatory structures. The United States' application of existing laws has also resulted in much greater clarity and speed in the implementation of controls on GMOs.

46. In the United States, there is no special regulatory system for ensuring the safe use of biotechnology in the laboratory or factory where the organism is not to be released into the environment[94]. The National Institutes of Health (NIH) have special guidelines[95] for laboratory or factory use that are implemented by most users of the technology. If an organism is to be released into the environment, then there may be three agencies which have oversight: the Department of Agriculture (USDA), the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA). The USDA, through the Animal and Plant Health Inspection Service (APHIS) is the lead regulatory agency for deliberate releases of genetically modified plants into the environment.

47. The information required for assessing or assuring the safety to human health and the environment under Directive 90/220/EEC and by the USDA appear to be almost identical and it is generally agreed that the assessment procedures result in very similar conclusions. In reality, most field trials in the United States are however only subject to notification, not assessment[96]. As a general principle, in the United States, the transfer of genes to plants which are not significant in agriculture is only important if there is a likelihood that the genes will cross back into the agricultural (managed) environment. APHIS's stated aim is not the protection of the environment but the protection of American agriculture[97].

48. The European regulatory system for releases into the environment requires a complete risk assessment to be performed by the applicant (and so differs from those countries (such as the United States and Canada) where government performs the assessment on the basis of information supplied by the applicant). The competent authority in the Member State applied to then audits the application to ensure that risk to human health and the environment has been minimised. In the United Kingdom, advisory committees have been allotted the role of examining the risk assessment and management procedures in applications and of advising Ministers or the Health and Safety Executive on whether to permit the genetic modification work to proceed and on any changes to the procedures that might be required to minimise risk. In the case of GM foods, the Government perform the risk assessment on the basis of information provided by the applicant.

### International requirements for the movement of GMOs between countries

49. Uniform regulatory standards for the movement of GMOs between countries are seen as a primary concern, mainly to ensure that trade barriers are not used as a means of arbitrary discrimination and covert protectionism. The 1996 UNEP guidelines[98] were, at United Kingdom instigation, an attempt to provide an internationally agreed minimum standard for the safe use of GMOs. Different safety standards may act, or be used, as barriers to trade and the GATT treaties require that the World Trade Organisation accept only "valid" scientific reasons before products can be prevented from entering the market in member countries. This raises the question of what constitutes a valid concern and by whom it should be judged.

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92 This policy was published as "*Co-ordinated Framework for Regulation of Biotechnology: Announcement of Policy and Notice for Public comment*", Federal Register, 1986.

93 United States Department of Agriculture, p 169.

94 Regulations made by the Occupational Health and Safety Agency, however, concerning general factory safety apply to biotechnology. Policies were made concerning the interpretation of these regulations in the light of the use of recombinant techniques, under the Co-ordinated Framework and published in the Federal Register at 50 FR 14468 (1985); 51 FR 23302-50; and 51 FR 25412 (1986).

95 The latest amended version (30 April 1998) of the current NIH Guidelines can be found in the Federal Register at 63 FR 26018.

96 Food and Drink Federation (FDF) Q 545.

97 APHIS provides a mission statement on the Internet at http://www.aphis.usda.gov/oa/mission.html. APHIS also has a wildlife services section, but this is not concerned with the impact of agriculture on the environment as opposed to the prevention of wildlife damage to crops and the protection of rare and endangered species.

98 United Nations Environmental Programme International Technical Guidelines for Safety in Biotechnology, 1996.

50. Discussions are currently in progress on a biosafety protocol to the Convention on Biological Diversity[99]. This protocol is expected to be agreed by a special conference of the parties to the Convention early in 1999. It seeks to regulate the cross-boundary movement of "living modified organisms" resulting from modern biotechnology. The protocol may succeed in providing a common definition of a "living modified organism"[100] and a workable system of "advanced informed consent" which would require the exporting country to provide the necessary safety information to the importing country.

THE PROPOSED REVISION OF THE DELIBERATE RELEASE DIRECTIVE, 90/220/EEC

51. The main elements of the Commission's proposed revision of the deliberate release Directive, together with the paragraphs of the opinion section of this report where they receive comment, are as follows:

*Risk assessment*

52. The revision would clarify certain terms and the scope of the risk assessment. The revision includes a statement of the principles on which the risk assessment should be based. It defines risk assessment as including direct, indirect, immediate and delayed effects (paragraphs 89–97).

*Product legislation*

53. The revision would exempt trial releases as well as marketing releases from the Directive if they were covered by other Community legislation for specific products with similar risk assessments (paragraph 108). (Product legislation exists for novel foods and for drugs. It is in preparation for seeds and animal feeds.)

*Monitoring*

54. The revision requires monitoring after a marketing consent has been granted. It defines the objectives of monitoring to include "any relevant direct, indirect, immediate or delayed effects on human health and/or the environment"[101] taking into account, if appropriate, potential for pathogenic, toxic or allergenic effects on human health; capacity for colonisation; potential to compromise the efficacy of therapeutic, prophylactic or diagnostic measures; potential to persist and spread in the environment; potential for interaction with target or non-target organisms; potential to affect population dynamics; effects of potential horizontal gene transfer; and the phenotypic and genetic stability of GMOs (paragraphs 102–104).

*Ethics*

55. The Commission would be able to consult any committee it establishes to advise on the ethical implications of biotechnology and on general matters that may raise ethical concerns (paragraphs 126–127).

*Public consultation, transparency and labelling*

56. The Commission would be required to make available to the public for comment the content of marketing notifications (paragraphs 118–123) and there would be greater transparency at Community level (paragraph 124). GMOs are to be labelled in accordance with Community policy, which has yet to be completed, but currently requires labelling where the gene or gene product can be detected (paragraphs 135145).

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[99] The Convention on Biological Diversity (Rio de Janeiro, 1992) (Cm 2127) is a binding agreement signed by over 170 countries (though not ratified by the United States). It came into force on 29 December 1993 (DETR pp 190-1). The Convention has three key objectives: (i) the conservation of biological diversity; (ii) the sustainable use of this diversity; and (iii) the fair and equitable sharing of the benefits arising out of the utilisation of the genetic resources. Article 19 Paragraph 2 of the Convention requires the parties to the Convention to "consider the need for and modalities of a protocol setting out appropriate procedures, including in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity".

[100] Products derived from but not containing a viable organism are not likely to be within the scope of the protocol.

[101] Proposed revision of Directive 90/220/EEC, Annex VII.

*Community scientific advice*

57. In the commercial release process, where an objection has been raised by a Member State, the Commission would be required to seek the opinion of the Community-level scientific committee on any case which is likely to have an effect on human health or the environment but the Directive does not specify the process by which the opinion would be taken into account or the time frame for the committee's consideration (paragraphs 163–164).

*Alteration of release procedures*

58. In the case of trial releases (deliberate release for the purpose of research and development), the revision would introduce, on the basis of experience and knowledge, two categories of application for release, those in the lower risk category being decided within 30 days. The procedures for these two categories would replace the current simplified procedures for research releases. There would in addition be a specific procedure for research releases in several Member States. For commercial releases, there would be the possibility of a simplified procedure for certain cases (paragraph 161).

*Comitology*

59. The deliberate release Directive confers certain implementing powers on the Commission which must be exercised in accordance with the "comitology" procedures[102]. The purpose of these procedures is to establish a committee structure, comprising national representatives under the chairmanship of the Commission, which ensures Member State involvement in the exercise by the Commission of its implementing powers. The present Directive provides for a "IIIa" (regulatory committee) procedure. The Commission is required to submit its draft implementing measures to the committee. If a qualified majority of the national representatives approves the draft measures, the Commission will proceed to adopt them. If, however, there is no qualified majority in favour, or the committee fails to deliver its opinion, then a proposal relating to the draft measures must be submitted to the Council of Ministers. The Council may adopt these by a qualified majority, or amend them by unanimity, but if it fails to do either within a three month time limit, the Commission shall proceed to adopt the measures.

60. The proposed revision of the Directive envisages switching from the IIIa to the IIIb regulatory committee procedure. The main difference is that the Council may prevent the adoption of a draft proposal referred to it by the Commission if a simple majority of Ministers opposes the draft. The effect of the change from a IIIa to IIIb procedure would be to strengthen the role of the Council by enabling it to exercise a decisive role in agreeing or blocking controversial implementing measures proposed by the Commission. It expands the options open to the Council by enabling it to agree draft proposals by a qualified majority, amend them by unanimity or reject them by simple majority (paragraph 162).

*Time limits*

61. The draft Directive introduces for the first time time-periods within which the Commission has to submit proposals on marketing notifications to the comitology committee (when an objection has been raised by any Member State) and to the Council, and within which the Member State competent authority must issue a consent following the Commission's decision. A mediation period is introduced in which Member States can seek to resolve differences in views about the advisability of marketing a specific GMO product (paragraphs 165–169).

*—Trial releases*

62. For a trial release, the applicant submits its risk assessment dossier to the competent authority within the Member State in which it wishes to conduct the trial. The authority has 90 days in which to deliver its decision, not including time when the applicant has been asked to provide further information. Within the first 30 days the authority submits the dossier to the Commission who circulates it to all Member States. Within a further 30 days Member States may comment on the dossier. The proposed multi-State release works in the same way, but happens in several States at once. The simplified procedure requires a competent authority decision within 30 days and the dossier is not circulated to other Member States.

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[102] Set out in the 1987 Decision (87/373/EEC) laying down the procedures for the exercise of implementing powers conferred on the Commission. Pursuant to Declaration No. 31 annexed to the Final Act of the Treaty of Amsterdam, the Commission has proposed amending this decision. This is the subject of a separate inquiry by Sub-Committee E (Law and Institutions).

*—Commercial releases*

63. For a commercial (marketing) release, the applicant selects a Member State to assess its risk assessment dossier. The Member State's competent authority has 90 days in which to make a recommendation. If the recommendation is to permit the release, the dossier and recommendation is circulated to the Commission and other Member States. Member States and the Commission have 30 days in which to comment or raise objections (If there is no objection, the original Member State issues a Community-wide permit.). If any objections are raised, there is then a further 60 days in which to resolve disputes. If objections remain, the Commission has three months in which it must submit draft proposals to a committee comprising representatives from the Member States but chaired by the Commission (the "comitology" procedure) and, where appropriate, consult its scientific committee. The Commission's proposal may be approved in the comitology committee by a qualified majority. If not so approved, or if the committee fails to act, the proposal is passed to the Council. The Council then has three months in which to accept the Commission's proposal by qualified majority, amend it by unanimity, or reject it by simple majority. If the Council fails to act or accepts the proposal, the Commission shall then implement it. If there is a simple majority against the proposal (assuming it was to permit the release with whatever conditions), then the application falls. Once a decision to approve has been made, the Member State applied to has 30 days in which to issue the consent. The clock may be stopped to request further information from the applicant and to consult the EC scientific committee. If the full procedure is used to its permitted extent, the minimum duration is a year and one month plus clock stoppages plus the time taken for the Commission to act after the Council has or has not taken a decision, which is not subject to a time limit but at present takes many months.

*Seven year consents*

64. The draft Directive introduces a seven year time period for consents to market and a new procedure for renewing marketing consents. Products already approved would have to reapply for approval seven years after the adoption of the Directive (paragraph 170).

## PART 3: VIEWS OF WITNESSES AND OPINION OF THE COMMITTEE

### POTENTIAL BENEFITS AND RISKS

#### BENEFITS

65. The potential benefits of the technology were described by Mr Galvin of the United States Department of Agriculture (USDA), who said that "these products, if regulated properly, offer significant benefits in the form of reduced chemical use, improved yields, lower production costs and enhanced qualities for consumers and other end users" (Q 374). We set out below some of the ways in which the technology may be of assistance to farmers, industry, consumers, the environment and the developing world, although the benefits are mainly for future delivery.

*Yield*

66. Whether by traditional breeding or by using genetic modification, the purpose of plant husbandry is to improve the quality of plants. One aspect of quality is yield and this has been the focus of the first commercial genetic modifications, partly due to the relative scientific simplicity of the modifications required. Monsanto claimed that genetic modification for herbicide tolerance and pest resistance (and now resistance to bacterial, fungal and viral diseases) resulted in fewer crop losses (pp 135–6). The yield improvement they identified was between 5 and 10 per cent. and this was backed up by the National Farmers' Union of England and Wales (NFU), who argued that production would cost less with, for example, reduced expenditure on herbicides and pesticides (pp 112–3). Genetic modification can be of particular help in cutting losses due to pests, where traditional breeding is impotent to develop resistance. As an example, nematode damage to the United Kingdom potato crop annually results in some £20 million of lost income and world-wide costs $60 billion. Some sources have estimated that insect damage annually results in crop losses of 13 per cent. world-wide[103]. The University of Leeds has found a rice gene that prevents nematodes from digesting their food and they are working on engineering it into other varieties of rice and other vegetables[104]. Another tactic for fighting disease is to insert marker genes into crops. These will enable farmers to identify disease at an early stage (for example, by producing a change in leaf colour or inducing fluorescence). Crops can also be made more resilient to the elements. For example, work is progressing on modifying crops to tolerate frost, partly through the use of genes found in fish (Professor Bainbridge, of the University of Teesside and chairman of the advisory committee on novel foods and processes, Q 681). In addition, the task of meeting future world food needs using existing technology may prove difficult (Zeneca, Q 59). The United Nations estimated the world population to number 5716 million in 1990 and 5768 million in 1996. Conversely, it calculates the world's arable area to be on the decline: from 1,381,983 thousand hectares in 1990 to 1,381,917 in 1996[105]. Any increase in food production must be achieved by means other than increasing the area of land under cultivation. Genetic modification is a technology which can assist with this (Professor James, of the Rowett Research Institute, Q 664).

*Added value*

67. "Biotechnology is an enabling technology that facilitates the breeding of new crop varieties with enhanced value" according to the British Society of Plant Breeders (p 298). The current emphasis on herbicide and pest resistance may be short-lived, as the technology is available to make much greater changes to the characteristics of plants (Professor Burke, of the University of East Anglia and former chairman of the advisory committee on novel foods and processes (ACNFP) p 9). It is likely that the changes will attempt to add value to high volume, currently low value, crops by, for example, changing the properties of the oil produced in oil seed rape or soya. In addition, crops will be able to be modified to fit a particular purpose more specifically than can currently be achieved (Food and Drink Federation (FDF) Q 541). Changes in nutritional value and in perceived quality of foodstuffs are already being developed, for example high starch potatoes (which absorb less fat when fried) and better tasting fruit achieved by slower ripening (Institute of Arable Crops Research, p 355; Zeneca, Q 60). These modifications may well be attractive to consumers. It is likely that crop plants, as well as micro-organisms, will be modified so as to produce pharmaceuticals. Mr Galvin provided us with lists of such crops on the market in the United States or in development (p 175–81). An example is *Laurical*, a low-cost raw material for soaps.

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[103] Biotechnology and Biological Sciences Research Council "In-gene-ious" exhibition.

[104] Centre for plant breeding and biotechnology, referred to in *BBSRC business*, July 1998, p 19.

[105] Food and Agriculture Organization of the United Nations, *Yearbook on Production for 1997*, Rome 1998.

*Environment*

68. The Government is conducting a review through the Pesticides Safety Directorate to determine whether herbicide use will rise or fall following the introduction of GM crops and whether the use of broad-spectrum herbicides is better or worse than current practice (Mr Rooker, Q 603). Experience in the United States, however, has shown that GMOs can reduce reliance on chemical inputs. United Kingdom bodies have predicted that this should be the case here (NFU, p 106; Statutory nature conservation agencies[106] (SNCAs), p 319). Farmers are able to spray with less herbicide on fewer occasions. The broad-spectrum herbicides used with GMOs generally degrade faster in the soil and are arguably less damaging than cocktails of selective herbicides (HMG, Q 467), though the actual impact of broad-spectrum herbicides is currently under study. Pest resistant plants do not require spraying with pesticide against those pests to which they are resistant and so insects which do not attack the crop are not harmed, unlike a pesticide spray (Professor Williamson, of the University of York, Q 501; SNCAs, p 322). Novartis noted that pest resistant cotton had reduced pesticide use by up to two thirds (p 372). In the future, less fertiliser than is used at present may be necessary. The United Kingdom is leading research into nitrogen-fixing wheat[107], though a result is not expected for many years. In addition to there being less residue of such chemicals on the crop, the pollution of ground water is commensurately lowered. As less spraying is required, tractors have to pass over the field fewer times and so the soil suffers less compaction and damage to its structure. In the United States, where field sizes are larger than in Europe, this has also resulted in less soil erosion, the introduction of "no till" agriculture and the use of significantly less fuel. It is the financial saving from these reduced inputs which has attracted United States' farmers to the technology (American Soybean Association (ASA), p 294). In addition, every yield improvement to existing agricultural land potentially means that less biodiversity-rich land such as rainforest has to be brought into cultivation (Monsanto, pp 138–9 et seq.). A recent United Kingdom trial of herbicide tolerant sugar beet has demonstrated that it can stimulate insect populations. As the weeds can be allowed to grow for longer (up until they start to compete with the crop), the bare earth which normally surrounds sugar beet has been replaced by a mulch of dead and dying weeds, a better environment for insects while also conserving water and reducing soil erosion. The mulch further encourages pests away from the crop and onto the weeds[108].

*The developing world*

69. Both the NFU and Professor James (of the Rowett Research Institute and chairman of a United Nations commission on future food needs) considered that the developing world has much to gain from both conventional plant breeding and biotechnology (p 106; Q 664). Genetic modification could assist developing countries to increase their domestic food production by widening the climatic range in which a crop can be grown or by increasing salt or drought tolerance (NFU, p 102). Pest management could be achieved without costly chemical inputs and the large proportion of crops lost to pests post-harvest could be limited[109]. Slower ripening could assist transportability and shelf-life. Dr Chesson, of the Rowett Research Institute, considered that thought had to be given to such countries' needs: he suggested that increasing the degradability of rice straw fed to buffalo could have a greater impact on Indian nutrition than increasing the seed content of the rice (Q 666). The fundamental issue was, however, how developing countries could access the technology. In this respect, Dr Chesson has concerns in relation to intellectual property (Q 666). Additionally, cost alone could deny these crops to peasant farmers. Professor James and Dr Chesson suggested that the agro-chemical/seed companies should be encouraged to take on scientists from developing countries to work on projects relevant to the developing world which would not otherwise receive priority. Such research should be funded by public-private partnership as it would otherwise not produce an economic return (QQ 665–6). They urged the United Kingdom Government to increase their assistance to developing countries to help them use the intellectual assets of British science to their benefit. Professor James pointed to some examples of successful partnership in Tanzania, Thailand and India (Q 664).

*Consumers*

70. The revolution in agriculture since the second world war has seen many improvements in the availability, range, quality, safety and costs of food. It is argued that this has been at a significant cost

[106] English Nature, Scottish Natural Heritage, Countryside Council for Wales and the Joint Nature Conservation Committee.

[107] A national research centre has been established at the John Innes Centre in Norwich.

[108] The Monsanto Roundup tolerant sugar beet underwent trials in Cambridgeshire. It has yet to be assessed as a commercial proposition.

[109] The Department for International Development is funding research into worms which attack rice.

in taste. The new technology aims to address the perceived loss of taste (Food and Drink Federation (FDF), p 332), by, for example, ensuring that fruit and vegetables are able to remain in the field longer. Zeneca's tomato is modified to ripen/rot slower, so it can remain on the vine for longer. This improves flavour as well as firmness and produces a "better" tomato paste (pp 22–4). Longer shelf-life and greater uniformity (particularly with respect to harvesting) should benefit the consumer through lower prices and, in the case of the tomato paste, already does: the modified version is sold for 20 per cent. less than the unmodified version[110] (Safeway, p 84). The technology will also make it easier to produce "convenience modifications", such as the seedless watermelon and tender-stemmed broccoli[111], which formerly could only be achieved by lengthy traditional breeding processes. Other benefits include healthier eating (through altered nutritional properties such as fat content) and reduced allergenicity (identifying those genes which cause allergic reactions in some consumers and removing or altering them). Work is in progress on a non-allergenic peanut (Professor Bainbridge, QQ 689–91). Lower levels of chemical residues, due to less spraying, will also result. There is however distinct consumer uneasiness at the introduction of the technology, noted by the Consumers in Europe Group (p 307) and the Consumers' Association (CA) (p 50). Professor Durant, of the Science Museum and Imperial College, London, considered that public confidence in the technology would best be secured by producing foods with "clear and demonstrable consumer benefits" (p 313). The Minister of State at the Ministry of Agriculture, Fisheries and Food (Mr Rooker) agreed and vigorously stated that the onus was on the biotechnology industry to develop products with tangible benefits (Q 604). United Biscuits argued that more products like the tomato paste with price, quality and taste advantages would assist consumer acceptance (Q 577). Professor Bainbridge suggested however that the majority of products which would be presented for assessment in the next few years would be commodity crops (Q 717), as this was the limit of the technology at the time of development. (See also paragraphs 118 to 124 and 128 to 145.)

*Industrial crops*

71. Plant varieties are already selected for particular industrial purposes. Genetic modification can be used to increase the efficiency of production of chemicals already extracted from plants by causing their "over expression"[112]. The high starch potato, engineered by the University of Oxford, is grown not for food use but for its starch[113]. Zeneca is developing a paper pulp tree with modified lignin to help produce paper using less energy and bleach (p 178). Plants (or more likely, micro-organisms used in containment (as with insulin)) can be modified to produce chemicals which they did not previously. Agriculture will change significantly as it responds to the new products which can be engineered into plants. Crops grown primarily for fuel (NFU, pp 112–3), for the manufacture of biodegradable plastics, pharmaceuticals and chemical raw materials are all possible. Monsanto has developed a blue cotton which much reduces the need to dye the product. Genes which produce proteins able to break down major pollutants into their component, non-toxic units may be useful on heavily polluted land (SNCAs, p 319). Plants which assist environmental clean-up are already in production, such as those which extract metals from the soil, useful for example for the reclamation of land contaminated by heavy industry.

72. **We consider that biotechnology in general and genetic modification in particular offer great potential benefits to agriculture, industry, consumers and even to the environment. The fruits of the technology should be available to our farmers, manufacturers and consumers.** These developments have to be surrounded by an assessment of risk (and, where necessary, its management), to which we now turn.

## Risks

*Human health*

73. The risks to human health of GM crops when eaten are considered in paragraphs 109 to 116. It has been argued that some modifications may, while in the field, pose risks to humans or unintended harm to other animals. This may be due, for example, to an increase in the allergenicity of pollen. These issues are considered and tested during trials and assessed in the risk assessment. Our comments

[110] The modified version is on sale in a larger tin (170g) for the same price as the unmodified variety (142g).

[111] Both are the result of traditional breeding.

[112] The switch which determines expression of a gene may be modified to increase the amount of protein produced beyond that which normally occurs – "over-expression".

[113] Starch is a significant industrial chemical, used, for example, in food production; medicine solubility; biodegradable plastics; packaging; and as a substitute for petrol based chemicals in paints.

relating to risk assessment must be considered as applying to this aspect of GM crops as much as to environmental issues.

*Environment*

74. The risk to the environment of GMOs is much more difficult to estimate than the effect on human health. Many modifications, such as slower ripening, are likely to have no effect at all, good or bad. The assessment of risk is also complex, for the intensification of agriculture has increased food supply and quality, but at a cost to the environment through chemical weed and pest control, the use of fertilisers, a reduction in the number of varieties of many crop plants in cultivation (Professor Williamson, Q 490) and a reduction in wildlife habitats. The risks of a GM crop must not thus be considered in isolation, but compared to the risks of current agricultural practice and an assessment of best practice. The risks posed by GMOs are, however, intangible and yet to be demonstrated (Professor Burke, former chairman of the advisory committee on novel foods and processes (ACNFP) and Professor Beringer, chairman of the advisory committee on releases into the environment (ACRE), Q 36). Many of the claims which have to date reached the headlines have been misleading[114]. Harm to the environment or otherwise by GM crops has yet to be demonstrated experimentally, but many of our witnesses believed that the following issues need to be addressed.

*—Out-crossing: can modified genes be transferred to other organisms?*

*—— Micro-organisms*

75. It is certain that gene transfer between micro-organisms takes place, but this has to be set in context (Professor James and Dr Chesson, QQ 641-3). It only causes a problem when the transfer is to a pathogenic organism or if the resultant organism is a pathogen. The transfer of genes from micro to higher organisms (such as plants) occurs only with very few bacteria such as *Agrobacterium*, used in one type of modification process[115]. Transfer from plants to bacteria is extremely improbable[116]. The possibility has however led to particular concerns about furthering the spread of antibiotic resistance through the use of antibiotic-resistant marker genes (Gene Watch, p 335). Recently an ampicillin tolerance gene was included within a transgenic maize. It was a bacterial gene, complete with a bacterial promoter[117]. ACNFP was concerned at the remote but finite possibility that the gene could be transferred to bacteria within the rumen of a cow which ate the maize as feed and concluded that it therefore constituted a hazard (Professor Burke, Q 35, also Professor Bainbridge QQ 693-4)[118]. An eventual decision allowing the use of this maize within the European Community was based on the presumption that the gene could be transferred, and weighed the consequences against the existing prevalence of ampicillin resistance within bacteria. Antibiotic resistant marker genes are not now used in new products (Dr Chesson, Q 669). **We consider that ACNFP was correct to proceed with extreme caution where the possibility of furthering antibiotic resistance was present[119]. In view**

[114] Two notable *causes célèbres* are those of lacewings which might eat the European cornborer, poisoned by Bt maize (a secondary effect) and the potato to which an immune system affecting lectin had been added. Swiss research has suggested that lacewings, if fed on the larva of cornborers, (which Bt maize is designed to kill) could also be killed, with potential effects on the entire ecosystem. ACRE was unhappy with the research, as, in practice, the lacewing would never gain access to the cornborer as the cornborer is inside the maize (see Novartis, pp 377-8). Scots research demonstrated that a lectin known to affect the immune system retained this characteristic when transferred into a potato, or mixed with potato. It was not and is not suggested that this lectin would ever be used in a food, and, were it to be, it is more than unlikely that ACNFP would approve it (see Professor James, QQ 637, 644).

[115] See paragraph 12 above.

[116] Genes in higher organisms tend to include regions of DNA that do not code for protein (termed introns). Bacteria are not able to translate these genes, hence expression is almost impossible. The promoter sequences in higher organisms are also significantly different from those in prokaryote organisms. Even where transgenes do not include introns, the probability of transfer of genes from higher organisms into bacteria remains extremely improbable.

[117] Novartis, pp 375-6 and Annual Report of the ACNFP, 1996, Appendix IV, pp 55-62.

[118] In 1994 ACNFP reported "on the use of antibiotic resistance markers in genetically modified food organisms". They concluded that antibiotic resistance markers in foods should be evaluated on a case by case basis and that the evaluation should include assessment of the clinical use of the antibiotic, the likelihood of transfer (and expression) of the gene into gut micro-organisms and the toxicity of the gene product.

[119] The events that led ACNFP to advise the United Kingdom competent authority to oppose the marketing of the maize are fully documented in the annual reports of the Committee for 1996 and 1997. ACNFP is however also correct in accepting that once the Commission, advised by its scientific committees, has decided that this gene and its product does not pose a risk (as the resistance is already widespread in the environment) it can no longer justify objections to products containing this or similar genes. See also the recent report of the Science and Technology Committee, 7th Report (1997-98): *Resistance to antibiotics and other antimicrobial agents* (HL 81-I).

**of the fact that alternatives are now available, antibiotic-resistant marker genes should be phased out as swiftly as possible.**

—— *Higher organisms*

76. There is evidence to show that DNA from any food can survive in a human's gut and even be absorbed by gut cells (Professor James and Dr Chesson, Q 639). The incorporation of such DNA into the genetic material of the cell must however be an extremely rare event (Q 640)[120]. We discuss this issue in paragraph 109).

—— *Transfer between plants*

77. Gene transfer is dependent on sexual compatibility and not all plants are compatible with each other, hence the limitations of conventional breeding. In the agricultural environment, genes may be transferred to similar crop plants in adjacent fields[121]. This is a hazard already faced by farmers growing similar crops at close quarters. Under normal circumstances, this would only be a hazard if the affected farmer retained seed for replanting in later years[122], but with those plants where the seed is the crop this would be a problem within the same year as seed on adjacent crops might inherit the transgenes and so alter the crop's characteristics. **As modifications become more varied this may have serious implications for what crops can be grown next to each other and for the retention of seed for replanting (see also paragraphs 105–106). Where plant-produced pharmaceuticals are concerned, we recommend either that these are grown indoors or that out-crossing should be made biologically impossible, by, for example, ensuring male sterility.**

78. The Soil Association saw the introduction of genetically modified plants into United Kingdom agriculture as the "most serious threat ever to the objectives and progress of the organic farming movement in developing and introducing viable systems-based approaches to agriculture" (p 390). The European Commission has proposed that products containing or derived from GMOs should not be allowed to be used for foods sold as organic. Professor Williamson however considered the organic movement's rejection of genetic modification to be unfortunate, as GM was compatible with sustainable lower input farming (Q 499). This view was reinforced by our visit to the John Innes Centre, when staff suggested and demonstrated that current GM crops were designed for more sustainable agriculture with less reliance on chemicals. To take the example of pest resistant crops, either a pesticide can be engineered into the crops (as with those using Bt) or the crop can be modified to attract insects which prey on the pest. **The latter method seems compatible with the principles of organic farming. Risk management procedures need to be employed to minimise transfer of the genes into adjacent crops, particularly those owned by other farmers. This is of particular importance where organic crops are grown, as drift of the transgenes into the seeds might result in harm to the property of the organic farmer. It should be a responsibility of farmers to prevent out-crossing (see paragraphs 105–107). We consider that GM technology may offer much to organic systems, for example through reduced inputs.**

—*Super weed*

79. If there are weeds which are sexually compatible with a herbicide tolerant crop (such as weed beet with sugar beet), the out-crossing of transgenes may cause significant harm to the agricultural environment (SNCAs, p 320), but only if other methods of control, such as selective herbicides, are not available (Zeneca, Q 89). Transfer of such genes into wild relatives in the natural environment could result in irreversible effects on natural vegetation (Dr von Schomberg, pp 401–2). There will however not generally be selection pressure to retain the transgene and it should in time disappear. **The transfer of herbicide resistance outside agriculture is unimportant in areas where herbicides are not generally used (for example field margins or woodland), but could cause control problems in areas dependent on chemical control, such as road-side verges, railway tracks or runways.**

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120 See also *New Scientist*, 31 October 1998 (No 2158), p 44.

121 Whether genes can be transferred depends on how closely related the parents need to be for a successful match and also on the pollen from the GM variety physically reaching the other plant. The distance over which pollen can travel is dependent on the crop and prevailing environmental conditions such as temperature, wind and insect populations. It is impossible to provide general figures for pollen viability, but MAFF recommends the following isolation distances for producing 99 per cent. pure seed: wheat, barley or oats, 2m or physical barrier; oilseed rape, 200-500m; sugar beet, 1,000m. A trial of one oilseed rape at the John Innes Centre found 0.0038 per cent. pollution at 400m, but this is only one variety in one particular circumstance.

122 Currently, for most crops, approximately one third of seed is retained.

80. A herbicide-tolerant crop may also establish itself as a weed and cause harm to the ecology and its processes within any ecosystem in which it stabilises (Royal Society for the Protection of Birds (RSPB), pp 384–5). Professor Williamson suggested that this cannot be predicted as there is some uncertainty as to what makes plants weedy. He suggested that the characteristics that would be expected to indicate invasiveness could not be expressed quantitatively (Q 505). In the agricultural environment, should a herbicide tolerant crop survive into the next growing season (described as a "volunteer"), it will pose weed problems for the new crop and may, if compatible, breed with it. This would increase the rapidity of multiple tolerances developing.

*—Multiple tolerances*

81. If varieties of the same crop are modified to express tolerance to a range of herbicides, gene-stacking may eventually occur (Iceland, p 64). This is where a plant develops resistance to a number of systemic herbicides commonly used in agriculture and effectively becomes less controllable. Zeneca noted that this is a longstanding agricultural issue (QQ 89–90) which requires that new agricultural chemicals be developed every decade[123].

*—Stress tolerance*

82. If a crop plant is modified so that it is able to be grown in new environments (geographical locations, altitudes, soil types, conditions of excess water or drought, or even different seasonal cropping) it may become a weed or pose risks to the environment into which it is newly introduced (Professor Beringer, Q 25; Professor Williamson, Q 505). Such a risk would need to be set against the benefit of the crop's introduction. Land on which wildlife depends, previously not used for cropping, may be brought under cultivation.

*—Pest resistance*

83. The development of pest resistance has so far focused on genes which produce the toxins derived from the bacterium *Bacillus thuringiensis* (Bt)[124]. These toxins are effective against a range of insects, particularly certain lepidoptera, but are harmless to plants and to humans[125]. They are used in a wide range of pesticides and the bacterium itself is used for pest control in organic systems. Pesticides are normally applied to crops at specific times during their growth and normally dissipate and are rapidly degraded in the soil. Conversely, plants which express pesticides are likely to do so uniformly, throughout the life of the plant, which may result in a greater likelihood of insects developing resistance to the effects of the toxin (Greenpeace Q116). GM crops may be much more effective at killing target insects and other susceptible insects and so deprive of food higher organisms which prey on them, such as birds (RSPB, p 386). On the other hand, the impact of pest resistant plants may be beneficial due to their selectivity, because the pest resistance only affects insects which attack the plant, as opposed to a spray which affects all susceptible insects in the field. Whether the net effect will be positive or negative has yet to be resolved.

*—EC and US: contrasting environments*

84. Changes in farming practice during the past 30 years have already had a significant impact on wildlife as, throughout Europe, it is particularly dependent on farmland (RSPB, pp 386–7). Farmland constitutes 70 per cent. of the United Kingdom's land area, much more than in the United States[126]. In addition, the use of agricultural chemicals per acre in Europe is much higher than in the United States. Due to both of these factors, sensitivity to the possible impact of genetically modified organisms on the environment may be much more significant within Europe than in the United States.

*Cartels and monopolies*

85. There is concern, shared by farmers, witnesses and ourselves, that the powers of a few agro-chemical/seed companies are already very great, and will become even greater, over the process of

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123 Mr Rooker announced to us that herbicides will require a separate approval to be used on GM crops (Q 603).

124 Products containing this organism constitute 80 – 90 per cent. of the microbial pesticides which are purchased and used. It was first registered in the United States in 1961.

125 POST, op. cit., p 12.

126 The Ministers were keen to note that not only did farming only cover 10 per cent. of the United States, but that "natural" countryside in the United States (for example the national parks, regarded as wilderness areas) was in completely separate areas (QQ 622, 634).

producing (developing and growing) genetically modified crops. United States soybean producers told us of their anxiety that in the future they would be growing specialised, value-added GM crops, the profit from whose added value would accrue predominantly to the companies rather than to themselves. Additionally, agricultural biodiversity (the number of varieties of a particular crop in production) may also be further reduced by consolidation in the industry when it is already an issue of concern[127]. **In this respect, the Seed Bank at Kew acquires added significance[128]. It is highly desirable that there should be competition between a sufficient number of companies on a world-wide basis. The degree of consolidation[129] is already much greater than that which obtains in the pharmaceutical sector and we consider that it should not progress any further. It is however a competition issue and should be dealt with by competition law. The multi-national aspect of the agrochemical/seed sector must not override regulation. Should agrochemical companies pursue research prohibited in Europe in countries which lack as stringent a regulatory system, we would deplore such actions.**

*One-use only crops*

86. GM crops introduced commercially in the United States have resulted in a change to farming practice in that farmers no longer have the right, or sometimes the ability, to retain seed for replanting the following year. This is either because the seed company insists on licensing the right to plant[130] or because the plant is male sterile, and so produces no seed. Where the crop is male sterile, this has the environmental advantage that out-crossing and back-crossing are impossible (NFU, Q 290). The American Soybean Association, in contrast to the NFU (Q 291), does not consider this to be a problem as they value the guarantee that all their seed is first quality and free from disease. They have chosen to purchase the entirety of their GM seed rather than follow their tradition of keeping up to two thirds of seed for replanting the following year. As value added products (such as altered oil property soya) are introduced, it will be important for the farmer to be certain of seed quality and origin to ensure that the desired modification is in fact present in the crop. This change-over from retention to non-retention of seed is not as dramatic as it seems, for many of today's agricultural crops are hybrids which lose their vigour (and hence their yield value) after the first use. **In relation to the developed world, so long as the farmer's economic prosperity is not unduly affected, we do not consider either the licensing of the right to plant or the sale of seeds which will produce sterile crops to be a problematic development. Both of these approaches should assist product traceability. In the developing world, however, many and probably most farmers would view the prospect of having to buy seeds each year with grave concern.**

*On balance*

87. **We recognise that there could be significant potential risks to the environment associated with the use of genetically modified organisms but are convinced that the benefits could be substantial in terms of yield, quality and new products. We agree with Professor Williamson that this technology is "certainly desirable" (Q 487), but is only likely to succeed if it gains widespread public acceptance and trust in its safety. The process of assessing risk is therefore of crucial importance to the future of the technology.**

88. Current risk assessment procedures for both trial and commercial releases assess solely the risks of allowing the release to proceed and do not consider any benefits. Many witnesses recommended that risk assessment should be replaced by "environmental impact analysis", which would take environmental benefits into account as well as risk (Novartis, pp 372–3). (If it is possible to identify environmental risk, then it must be possible to identify environmental and other benefits.) "It would be useful, therefore, if both regulators and consumers were able to balance potential risk against possible benefit" argued Dr Gliddon (pp 340–1). **We consider that environmental risks and benefits should be assessed at the same time.**

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127 See, for example, Professor Williamson on the traditionally bred Texas Cytoplasm corn, p 214.

128 As a resource for future breeders, so that they are not limited to varieties currently in production, but have access to the widest possible gene-pool.

129 Furthered both by Monsanto's acquisition of Plant Breeding International, Cambridge and by the agreement between Novartis and Hoechst during the course of this enquiry.

130 The seed bag for Monsanto's Roundup Ready soybeans in the United States bears the message "These seeds are covered under U.S. patent 4,535,060 4,940,835 and 5,352,605. The purchase of these seed convey no license under said patent to plant these seeds. A license must first be obtained from Monsanto Company before these seeds can be used in any way."

RISK MANAGEMENT AND SAFETY

89. **The risks involved in genetic modification can, we believe, be controlled, if a strict risk management process is in place. Such a process includes hazard identification, risk assessment, procedures to minimise risk and systems for disaster management. In examining these issues, we first questioned whether the current regulatory approach was appropriate.**

*The risks are not unique to genetic modification*

90. **In much of the evidence we received, witnesses did not distinguish between risks inherent in or particular to the new technology and risks present in standard agricultural practice, when most of the processes used in agriculture may face the same criticisms as those levelled against the agricultural systems produced by the new technology. Genetically modified organisms therefore need to be placed in the context of their agricultural use. Risk assessment is inadequate if it considers a crop in isolation. In assessing risk, we recommend that modified plants and their management schedules[131] should be compared to the use of a similar non-modified crop and best agricultural practice. The comparison should take account of the chemical usage and agricultural practice involved in growing both crops. For example, any negative effects of a pest resistant crop must be weighed against the use of the conventional pesticides on a conventional crop. It is encouraging to see that this is to be the approach taken by the Pesticides Safety Directorate (Q 603).**

91. Some countries have adopted systems which consider the risks associated with the introduction of new varieties of crop plants into the environment. The Canadian regulations are not specific to GMOs and evaluations "are conducted on the basis of the unique characteristics of each product rather than the method of production. All plants with novel traits are assessed for possible impacts on the environment based on the specific modification and the biology of the plant" (p 300). **While favouring the Canadian approach, we recognise that it is unlikely to secure acceptance in Europe. We recommend however that there should be triggers other than genetic modification which bring the assessment and management system into action, as is the case for novel foods. We recommend that, from now on, any crop with novel traits (or novel to a particular environment) which may have the potential to impact significantly on the environment should be subject to an oversight system. For example, conventionally bred herbicide tolerant crops are currently not subject to a monitoring programme. We consider that they should be subject to the same monitoring under the same systems as a GM herbicide tolerant crop.**

*Risk assessment*

92. The risk posed to the environment by every genetically modified plant is assessed before it is released. Normally, the assessment attempts to quantify risk and therefore, if necessary, enables risk management to minimise the impact on the environment. There are however differences in understanding of what constitutes risk amongst the Member States of the Community and as to what is and is not a valid risk assessment consideration (Green Alliance, pp 72–3; Dr Gliddon, p 340). Professor James called for an agreement (at EC level) on acceptable risk relating to GMOs (Q 672). Until this was resolved, there could be little progress with consensus. **We agree. In this respect, the Commission's attempt to define risk assessment principles is a much-needed part of the revised Directive. If approvals are to remain Community-wide, there must be a recognised standard as to what constitutes an unacceptable effect of a release.**

93. The principles of risk assessment identified in the draft Directive were however seen to be unacceptable by some witnesses. While agreeing that the principles and their application need to be standardised, the proposals were not seen as meeting the requirements for scientific evaluation, the needs of industry or the concerns of the public. Professor Williamson believed that the annexes which attempt to define the principles and information requirements "are so hopeless that they should start again from scratch" (Q 531). Dr Gliddon suggested that annexes II and III of the draft Directive "should be structured so that they can be directly related to the definition of the actual hazards related to the application". In addition he recommended that "a new annex III that is specific for multi-location, large scale marketing applications should be elaborated" (p 341). He also criticised the annexes for not providing a clear link between the information required and the risk analysis that follows. **A clear, coherent set of principles for environmental impact analysis is needed which allows for consistent interpretation by Member States. The annexes must be redrafted in order to ensure that the principles underlying the impact analysis have the widest possible acceptance.**

[131] Any conditions attached to the release and the general principles for handling a particular variety of modification. See paragraphs 105-106.

*—Indirect and cumulative effects*

94. The greatest present gap in the risk assessment as practised by the EC and United Kingdom today is that there is inadequate consideration of indirect and cumulative effects (Green Alliance, p 72; CWS, p 310). This is more important when considering licensing for commercial use than for trial releases, as the latter involves a particular experiment in a particular location (DETR, p 187). **We recommend that risk assessment procedures should consider the ecological effects which arise from the inclusion of herbicide tolerance and pest resistance into crops (SNCAs, p 318), as well as the changes that are likely to arise as further variants of major crops become available. Major changes to crop management, which might include alterations to normal rotation schedules, may have an impact on the environment which need consideration when assessing risk. The issues of the super weed, multiple tolerances, pest resistance and indirect agricultural and ecological effects could conceivably become problems if indirect and cumulative effects remain outside the scope of risk assessments. We recommend that, as proposed, the risk assessment should include direct, indirect, immediate and delayed effects, but the manner in which risk assessment is related to impacts on biodiversity, sustainable development, agronomic and conventional agricultural practice must be clarified (Dr von Schomberg, p 404).**

95. Once a crop has been approved for commercial release it forms part of the environment and risk assessments for the introduction of subsequent crops have to take its presence into account. Thus, in considering the potential environmental impact of a crop modified to tolerate a herbicide, the risk assessment must take into account the environment, including other sexually compatible herbicide resistant plants. **We recommend that a regulatory system which attempted to predict interactions of this sort and attempted to identify an integrated approach would be preferable to what amounts to a first come, first served approach. At the simplest level, guidelines could be set as to which herbicide tolerances might be incorporated into which crops, for example herbicide x into wheats and herbicide y into oilseed rapes. This would enable effects on, for example, rotation sequences to be anticipated and planned.**

*Uncertainties and the precautionary principle*

96. Thorough though it may be, risk assessment is but the first part of the process. Although it is possible to identify in a qualitative manner many of the hazards which might result from the use of GMOs, Dr Gliddon noted that it was difficult to quantify their impact (p 342) and there were strong calls for risk management procedures to acknowledge the inherent uncertainties (CA, p 52; Green Alliance, p 74). The Consumers' Association was critical when commenting on the methods used for managing risks, arguing that there are limitations to our scientific knowledge which mean "we do not always know what we do not know". While scientific advice is an essential part of the decision making process, it has limitations which mean that "it is not always sufficiently developed to be the sole basis for decisions" (p 52). The impact of new organisms released into an ecosystem can follow so many paths that scientists can only rely on judgmental analysis and on reasoning by analogy (Greenpeace, p 33). Professor Williamson provided us with a number of examples of introductions into similar environments that had substantially different impacts (p 213; Q 533).

97. The Directive has been seen as the first attempt to implement the precautionary principle[132] in regulation (Dr von Schomberg, pp 401–2). The United Kingdom has interpreted the principle to mean that a "step-by-step" and "case-by-case" approach should be taken when releasing genetically modified organisms into the environment. The Minister for the Environment (Mr Meacher) illustrated this by saying that "practical evidence on safety" was required before deciding whether to allow a commercial release (Q 603). Professor James and Dr Chesson were however concerned that the principle might be taken to an extreme and become an excuse for inaction (Q 669). It is recognised that the data on which to base a risk assessment is not available purely from laboratory experiments and thus in many cases a limited environmental release is needed in order to gather information so as to decide on the safety of subsequent, larger-scale releases. The precautionary principle is meant to be implemented in the United Kingdom (DETR, Q448; CA p 50), but its step-by-step approach can only work if the results of each trial release are used to identify safety procedures for (or the inherent safety of) subsequent experiments and if uncertainties are acknowledged (Green Alliance p 73). **In the same way as common principles are being agreed for risk assessment, the Community should try to agree an understanding of the precautionary principle, lest it become an excuse for inaction and nothing be allowed to proceed. The result should be a clear understanding of a step-by-step, case-by-case approach.**

[132] See paragraphs 41-42.

*Is a moratorium needed?*

98. The initial focus on herbicide tolerance and pest resistance, both of which have potential environmental impacts, has been seen by many as sufficient to justify a moratorium on commercial releases into the environment until the issues have been researched and clarified (SNCAs, p 319). Trial releases are designed to minimise risk and therefore do not generally provide enough information on ecological or agricultural disruption to be useful for identifying risks to the environment of larger scale, uncontrolled releases (as with commercial exploitation) even if monitoring was required. Professor Beringer considered that trial releases tell us that the plant is growing properly, but provide little evidence as to ecological behaviour (Q 9; also Professor Williamson, Q 505). Plant variety registration trials ensure that the plant is uniform and stable, but remain too small to provide data on the environmental impact of the introduction. Professor Williamson suggested that the data could only be obtained through the monitoring of large scale releases conducted on a commercial scale (QQ 507–9) (see also paragraph 98). Professor Bainbridge was opposed to a moratorium on the grounds that what was needed was more research, not a halt to it; that it was possible that the end of a moratorium would never be triggered; that we had to be mindful of competitiveness; and that a moratorium could not be enforced globally (Q 716). **We agree with those witnesses who said that large-scale trials were necessary[133]. The knowledge of how a crop grown on farm and commercial scales will interact with the environment can only be acquired by growing it on such scales. We consider that an outright moratorium would be inappropriate.**

99. The Government now appear to have reached agreement with the industry on a way forward. Herbicide tolerant crops are to be put on trial on a "farm-scale" basis prior to making them available for widespread use and research is to be conducted into the agricultural system which results from their use (Mr Meacher and Mr Rooker, Q 603). **The time-scale for the farm-scale trials is unlikely to cause much additional delay to the commercial exploitation of GM crops as EC marketing approvals and commercial availability of suitable varieties and seed would, in the normal course of events, be unlikely to enable them to be used sooner. If all proceeds according to plan, this is a satisfactory solution, even in relation to pest-resistant plants which are to be subject to a three year restraint. We must however be sure to avoid any unnecessary delay which might jeopardise the position of our farming industry. Additionally, detailed targets must be set for what is to be achieved during this period and the appropriate research must thus be commissioned at the earliest opportunity. Such a period loses its utility if such objectives are not set.**

*Commercial releases*

100. The draft Directive provides the means to approve commercial releases subject to conditions; in particular, modified crops would have to be monitored for direct and indirect effects on the environment. **We welcome the ability to set specific conditions for each release. The Community should set any compulsory conditions and these should then be able to be strengthened by Member States if desired[134]. This facility can also be envisaged as a way to gather the fullest environmental data while allowing commercial releases to proceed faster than has occurred to date.**

101. **We are however concerned that the draft Directive does not envisage an end-point at which the GM crop is considered safe enough to be released into the environment without such constraints (though perhaps with certain management conditions[135]) (see also *Seven year consents*, paragraph 170). After an initial, monitored commercial release, the product (if judged to be safe) should be granted an open-ended commercial licence, subject only to any necessary management conditions and the requirement to inform the competent authority of any data which requires a change to the environmental assessment. Additionally, many future modifications (such as soya with altered oil properties) may not have the environmental implications of herbicide tolerant and pest resistant crops and, subject to satisfactory trials, should be able to bypass the initial form of commercial release and be placed on the market without restriction. This is especially important as, if it is felt necessary to set conditions for every release, it is possible that cases of genuine concern will not be discerned from others.**

[133] This is particularly the case to identify any effects of the modification which remain unobserved following the laboratory to trial release stages (see paragraphs 11 and 19).

[134] For example, due to particular environmental sensitivities.

[135] See paragraphs 105-107.

*Monitoring*

102. The statutory nature conservation agencies recommended statutory monitoring until there was clear evidence that GMO systems were viable, safe and sustainable (p 318). Novartis commented that the absence of rules for monitoring after commercialisation is a major current flaw. "There is a broad consensus in the field that good monitoring makes good business sense as well as being environmentally sound" (pp 372–3). The draft Directive requires applicants to provide a detailed plan for monitoring to include "direct, indirect, immediate or delayed effects on human health and/or the environment"[136]. **Monitoring is not a substitute for risk assessment but can complement it. We consider that those involved should report on any predicted effects which do not occur and any unexpected events which do occur. For trial releases, nil returns should also be required, so that those monitoring have the fullest information possible. The permit-holder must be reminded that any information which might modify a risk assessment and risk management requires a modification of the consent and that they must inform the regulatory authorities. We are concerned that the Directive's recommendation is for the applicant (the seed company) to perform the monitoring, without the intervention of any outside body, whether as monitor or auditor[137]. We recommend that monitoring (to Community-wide standards) should be performed by an independent organisation, funded through levies on applicants. If a dedicated monitoring organisation is not to be established, the tender might be given by Member State governments to universities. There must also be a Community-wide audit of enforcement as monitoring standards (in many fields) have in the past been subject to too great a variation.**

103. **While detailed monitoring as proposed is appropriate and feasible for trial releases and probably for the initial phase of commercial releases (along the lines indicated by Mr Meacher (QQ 611–12)), where full commercialisation is concerned the product is presumably already judged to be stable and safe and large geographic areas are likely to be involved. At this point, farmers are in a good position to notice the unusual and problematic, but they would need much agronomic and ecological assistance, particularly on what to look for, how to report and to whom, especially where they are asked to note the impact of their crops on the non-agricultural environment. Those involved in setting up these structures could learn from the approach adopted throughout the world to monitoring pharmaceuticals, the adverse reaction reporting system[138], whereby doctors[139] report perceived adverse reactions in patients. In the United Kingdom, these reports are then investigated and corroboration is sought from the General Practice Research Database. Supervision, for GMOs at present conducted by the HSE, would also be necessary as the system should not be solely dependent on spontaneous response. In any event, it would be irresponsible to require monitoring without first considering the consequences and structures which need to be in place, or without setting specific, measurable objectives. An absence of adverse results, through the use of very few (or inappropriate) indicators, is likely to breed false confidence that nothing is wrong.**

104. **Everyone acknowledges the importance of monitoring, but it is a costly exercise. If the cost of monitoring is to be borne by the agro-chemical/seed companies, (who are but one part of the chain which benefits from genetic modification) it must be done responsibly and even-handedly. Professor Bainbridge considered that, while erring on the side of caution, we had to be mindful of issues such as industrial competitiveness (QQ 673, 716) (see also paragraph 171).**

*Conditions attached to releases*

105. **Conditions and regulations should only be imposed where necessary, that is, consistent with the precautionary approach, but must be adhered to when imposed[140]. We should remember that, as well as dealing with the regulation of a new technology, we are dealing with products dependent on commercial success. It is likely however that each type of modification (for example herbicide tolerance) will need to be subject to general conditions as to its handling and that each particular crop may require some specific conditions dependent on its characteristics.**

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136 Proposed revision of 90/220/EEC, Article 11.2d and Annex VII.

137 Professor Bainbridge argued that monitoring without independence would not gain consumer acceptance (Q 726).

138 Run by the Post Licensing Division of the Medicines Control Agency.

139 The pharmaceutical companies themselves are not in a position to monitor as they do not have the same access to field data. They are, however, under an obligation to collate world information on their products and submit it to the competent authority within 15 days.

140 We understand that some prosecutions may be imminent for breaches of consent, and support this enforcement.

106. **The general conditions may best be established through a (preferably pan-European[141]) government-sponsored code of practice. Farmers and industry are in need of comprehensive, standardised guidance as to how to handle GM from seed sack to shop shelf. Such a code needs to embrace, amongst other things, buffer zones[142] between crops, the use of non-selective herbicides (perhaps once in a given crop rotation), rotation sequences[143], refuges[144] of non-GM or untreated crops, geographic zoning[145], farm saved seed and (if required) traceability[146]. Finally, the code should include a plan for recovery in relevant situations.**

107. The Government's approach has been to urge biotechnology's proponents (in the form of SCIMAC[147]) to prepare a code and then the Government will assess the finished product to see whether it meets their approval (QQ 603–4). Professor James argued that all sides of the debate needed to be involved (Q 669). **We welcome the work being undertaken by SCIMAC to deliver a code with the support of Government. The statutory nature conservation agencies and other groups should certainly be involved as the code is unlikely to command authority unless it is agreed by all sides in the debate. It may be the case in this instance that a voluntary code of practice will not be sufficient; if so, current practice in relation to pesticides (a code of practice backed-up by regulation) should be adopted.**

*Product legislation*

108. The DETR was concerned at the Commission's intention to remove from the scope of the Directive trial releases where the product is covered by product-specific legislation (Dr Smith, Q 435). Professor James was also concerned that the move to product legislation could result, at Community level, in issues falling between the gaps of committees' remits (Q 663). Dr Chesson recommended a one stop process whereby a composite committee responded to all the different pieces of vertical legislation (Q 663). **We share these concerns. Trial food crops are not food, and it is their impact on the environment that is important rather than their qualities as a food. Each product must be considered within the terms of the most appropriate legislation, and for products under development released into the environment this is the appropriate legislation. For commercial releases, however, product legislation is indeed more appropriate, provided that there is a comparable risk assessment and management process.**

## GM FOOD

109. In the public's eyes, concern at environmental safety is only half of the GMO problem. References to "Frankenstein foods" have created doubts as to whether a pizza containing GM soya, tomato and cheese is as safe to eat as conventionally produced foods (Greenpeace, Q 115). It should however be noted that "many products from GM plants, such as sugar prepared from GM sugar beet, are absolutely identical to conventional products."[148] Additionally, the majority of GM foods will not contain viable genes or DNA[149], although the issue of whether these might be transferred to humans has vexed the public. It is acknowledged that DNA can survive in human saliva for up to twenty minutes and in the stomach for up to eight seconds. Similarly, there is evidence for uptake of DNA by

[141] Lest any aspect of the resultant code be considered in restraint of trade.

[142] The distance between a GM and the next crop to ensure low pollen transfer rates. This issue is but one example of the complexity of the issues which must be considered before products reach the market. The distance of the buffer zones must be determined, as must which crops may be grown in what proximity to each other and how to resolve disputes between farmers. What level of genetic transfer constitutes pollution must also be determined. Should the level of certified seed purity (95 per cent.) be acceptable in the field or is this inadequate where value-added crops with highly specific products are concerned?

[143] The order in which GM crops can be planted.

[144] In relation, for example, to pest resistant crops, the area of the field which should be planted with non GM crop to slow down the development of resistance.

[145] Whereby, for definite reasons, use of a modified crop is restricted to a Member State or area of a Member State. Zoning is already in operation for conventional crops in the United Kingdom, for example the separation of conventional rape from high erucic acid oilseed rape is guided by the Essex Seed Zoning Committee.

[146] See also paragraph 117.

[147] The Supply Chain Initiative on Modified Agricultural Crops. The body's membership includes the NFU, BSPB, British Agrochemicals' Association, UK Agricultural Supply Trade Association and the British Sugar Beet Seed Producers' Association.

[148] Royal Society statement on "Genetically modified plants for food use", September 1998, p3.

[149] For example, tomato paste does not contain viable DNA due to its processing, whereas fresh tomatoes do contain viable DNA.

micro-organisms and human cells. Indeed, Dr Chesson argued that this was a "perfectly natural event which has been occurring throughout human kind". There was no evidence however for the incorporation of such DNA into human cells' genetic material (Q 639). In the Royal Society's words, "it is worth remembering that the medical profession have been trying to develop ways to insert genes into the body cells of humans for some time, with so far rather limited success. We are not aware of any evidence for transfer of intact genes to humans, either from bacteria in the gut, or from foodstuffs such as potatoes, wheat or chickens, despite daily consumption of DNA in the diet."[150] The transfer of genes between higher organisms depends on the probability of sexual crossing. Natural sexual barriers mean that it would be extremely rare for any gene (including transgenes) to be transferred between non-sexually compatible plants let alone between plants and animals. The fear that transgenes may be transferred to humans by eating GM foods seems to be unfounded.

110. In any event, generic statements about the safety or otherwise of GM foods cannot be made: each novel food has to be assessed on a case by case basis (Professor Bainbridge, Q 677; Dr Chesson, Q 645; also Professor James, Q 637). Additionally, it is not so much the source of the gene which is important, but its behaviour in the new organism and the characteristics which result (Professor Bainbridge, Q 681). **The emphasis should not thus be on "genetically modified" but on the new characteristics of any individual product.**

111. All GM foods[151], whether grown in the EC or imported, are subject to an assessment (additional to and completely separate from the assessment for environmental safety) under the EC's Novel Food Regulation (and accompanying documents[152]) which meet World Health Organisation standards (Mr Rooker, Q 603). In the United Kingdom, the Advisory Committee on Novel Foods and Processes (ACNFP) assesses such applications (see paragraph 37) and can refer issues to other committees[153]. ACNFP has not been subject to the same criticisms as ACRE (see paragraphs 148–153) and its practice is generally commended (Professor James, QQ 648–9). There is cross membership between ACNFP and the other food advisory committees such as the committee on toxicology and the committee on medical aspects of food policy[154]. An ethicist sits on ACNFP and there is consumer representation on each committee (Mr Rooker, Q 607; Professor James, Q 648). ACNFP will eventually be responsible to the Food Standards Agency.

112. The food is rigorously assessed for safety before it is approved or rejected. The level of surety and safety required was illustrated by ACNFP's chairman, Professor Bainbridge, who said that if the common (unmodified) potato were to come before the committee, it would not today be approved (Q 676). She argued that we know far more about novel foods than many of the staples of our diet and that novel foods which have been approved are at least as safe as their non-GM counterparts (Q 675). Intentional and unintentional changes are examined, as are the levels of key nutrients. The nature of the transgene is examined as is its level and expression. The food is tested for, amongst other things, stability, toxicity, allergenicity and mutagenicity (Zeneca Q 85; DETR Q 448; Professor Bainbridge, QQ 674–5, 685–7). Additional questions must be satisfactorily answered which are specific to each application (Dr Chesson, Q670).

113. Any risk to human health may usually be attributed to known properties of the parent organism and of the transgene. The behaviour and track record of the gene in the donor organism can be studied and compared with the new organism. In relation to allergenicity, for example, assessment is based on the allergenic potential of the donor[155] and comparison of the transgene with genes known to produce allergic reactions[156]. Should the transgene not have a previous history of food use[157], while assessment would similarly be based on comparison and prediction, the appropriate outstanding information would also need to be gathered through testing (Professor Bainbridge, Q 685). The Royal Society is of the opinion that this approach may not be adequate in the future, should the use of genes without a history of food use become commonplace. Their statement considered that: "the current

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150 Royal Society, op. cit., p 7.

151 This includes GM foods which are identical to their unmodified equivalents, such as highly-refined oils.

152 (See paragraph 37) 97/618/EC Commission recommendation of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation 258/97/EC (OJ L253 (16 September 1997) p 1).

153 For example, to the committee on toxicology (Professor Bainbridge, Q 687).

154 The is also cross-membership between ANCFP and ACRE.

155 Some organisms (for example, peanuts and shellfish) will clearly be "off limits" as donors of genes.

156 See Dr Chesson, Q 647.

157 Most of the genes being inserted at present already have a history of food use.

system of relying on identification of known allergens in the GM plant, coupled with the reliance on 'substantial equivalence'[158] may result in potential allergenicity problems being impossible to predict if there are no data available on the substances in question, particularly since the mechanisms of allergenicity are often poorly understood.". This was however put into context by Dr Chesson, who noted that, because the tests do not operate in isolation, if an allergic reaction was not predicted, any problem would surface during, for example, toxicity testing (Q 647). Professor Bainbridge argued that the system worked as well as it could in relation to assessing allergenicity[159] (Q 689). She recommended however that regulators should prepare for the situation identified by the Royal Society by establishing databases to compile pertinent information and allow it to be shared world-wide, so that regulators had access to the widest possible range of data (Q 685).

114. There has also been disquiet over furthering the spread of antibiotic resistance through the use of antibiotic resistant marker genes[160] (GeneWatch, p 335) and we considered this issue in paragraph 75. **Antibiotic-resistance marker genes should be phased out as swiftly as possible.** Those developing GM crops have, in any event, now successfully developed alternative marker genes (Dr Chesson, Q 669).

115. General concerns relating to unforeseen longer term effects have also been raised, especially in relation to the ability of scientists to predict the effects of the technology (Greenpeace UK, p 33, Q 101; CWS, p 311) and indirect effects of GM foods which may not manifest themselves for a very long period of time. These indirect effects would not be due to the safety of the technology, but the changes to diet and nutrition which may result from it. For example, if the quantity or type of fat in the diet is much reduced by means of GM food or otherwise, there may be long term health consequences. Foods which have long been available are not (and have never been) subject to the same care relating to their short or long-term safety as novel foods, whether genetically modified or not.

116. **We consider the regulatory process for assessing the safety of novel foods to be thorough and proper and we see no reason to doubt the safety of foods which have been approved by the regulatory process. All genetically modified foods on sale in the United Kingdom have been approved by this process and, as the FDF noted, by approvals processes around the world (Q 543). We consider that research needs to be conducted into how best to consider applications involving genes without proven track records of food use. We support the call for the accumulation and sharing of national data to assist regulators[161]. Any long term effects of GM foods are likely to be the result of changes in the nutritional content of those foods rather than the GM method by which the foods are produced.**

*Traceability*

117. Mandatory traceability must not be confused with "identity preservation" which is discussed in paragraph 131. Traceability is when the lineage of a finished product can be traced back to source. Were it to be required, it would primarily facilitate long-term monitoring for health effects of GM foods and product recall in the event of any adverse health effects. For this reason it was advocated by some witnesses (CEG, p 308; CWS, p 311; Safeway Q 250; NFU Q 311). ACNFP has yet to decide how GM foods ought to be monitored in the food chain[162], but Professor Bainbridge suggested that a lot could be learnt from analysing existing data (such as that possessed by supermarkets) rather than requiring new information to be gathered (Q 724). Mr Rooker indicated that the supermarkets were willing to share their data on consumption habits, collected through the use of loyalty cards (QQ 607, 611). **Genetic modification does not concern a single product or variety but will soon affect the whole spectrum of agriculture. To require traceability for all agricultural commodities would be an exceedingly costly exercise[163] for little benefit, especially when there is no anticipated risk to human health. Furthermore, GM is but one technology applied to agriculture. It would be irrational to require the traceability of GM products but not those**

[158] "Substantial equivalence" is used by the Novel Foods Regulation (268/97) to attempt to differentiate between those foods considered to be novel and thus require assessment and those which are similar enough (substantially equivalent) to foods already generally in use within the EC and thus do not require novel food assessment.

[159] Professor Bainbridge also suggested further research into other aspects of the issue of allergenicity, especially into why allergies develop. Monitoring would be of assistance in this (Q 689). See also paragraph 117.

[160] For an explanation of the use of marker genes, see paragraph 12 and POST, op. cit., pp 4, 20-1.

[161] See paragraph 113.

[162] Mr Rooker suggested that it might involve supermarket databases on consumption habits (QQ 607, 611).

[163] Especially when the scale of production in America is considered.

**treated with novel fertilisers, preservatives or pesticides. Product recall is already possible without traceability[164] and in the remote event of there being a detrimental effect on human health an immediate and total recall would be necessary. A partial recall would only work if the system was precise and perfect and this could never be ensured. Traceability, though a theoretical asset, should not thus be required. Moreover, it is difficult to see how traceability could be achieved in the light of the quantity of imports likely to enter the Community from third countries, especially when those countries have deregulated GM crops (USDA, p 169).**

FURTHER PUBLIC CONCERN

*Public response to genetic modification*

118. Before considering what response to make to the public attitude towards genetic modification, it is as well to investigate the public perception of science and biotechnology. Recent United Kingdom research submitted to the Committee by Professor Gunter, of the University of Sheffield, suggests that although more than half of the population is aware of "biotechnology", few have any clear understanding of its scope. Biotechnology is correctly associated in the public mind with activities such as cloning and genetic modification, but also wrongly with, for example, the use of pesticides in farming and the application of preservatives to food. There is no clear concept of "genes" being part of the natural order; indeed, there is a perception that they may be unique to modified organisms. Many consumers believe that genes are only present in GM foods and are scared at the prospect of catching them should they eat the modified food (see paragraph 109). The "tampering with nature" involved in biotechnology is regarded by many as potentially risky and fraught with ethical problems (pp 342–3).

119. The recent Eurobarometer 46.1 survey on "The Europeans and modern biotechnology"[165], brought to our attention by Professor Durant, indicated that a majority of Europeans think that the various applications of modern biotechnology will benefit society; however, the applications considered least useful and most risky are perceived to be those in food production and the introduction of human genes into animals to produce organs for transplant to humans (pp 312–3). The public embraces eagerly each further scientific advance in relation to medicines, but is much less willing to do the same for foods. The survey showed that the public believes that risks outweigh benefits for the genetic modification of plants where these are crops in the human food chain, but the modification of flowers and ornamental plants was, however, perceived as beneficial (pp 343–4). Only 30 per cent. believe that some degree of risk is acceptable in order to increase economic competitiveness. 74 per cent. of Europeans questioned in the survey believed that genetically modified food should be labelled. Attitudes vary between Member States, with the greatest lack of enthusiasm for biotechnology and its agricultural and food applications in Austria, Denmark, Germany, Luxembourg and Sweden (p 312).

120. All the major consumers' organisations in the United Kingdom have expressed unease at the use of biotechnology in agriculture. While recognising the potential benefits, the Consumers' Association believed that there were ethical concerns and that there was a need to ensure adequate safeguards. They were convinced that consumers must be able to choose whether to accept or reject GM foods (p 50). The Consumers in Europe Group expressed support for the use of biotechnology in agriculture on condition that it was closely controlled (p 307). They stressed that "the consumer interest must be represented in the approval process to ensure the safety of new products and processes, to maintain and open up choice, to create access to information on the novel foods and processes used to produce them, and to protect the environment." To achieve this there was a need for a food approvals process based on sound scientific evaluation (p 308). **While the working of the Community systems can be criticised (paragraphs 164–165), the United Kingdom already has a sound system for the approval of novel foods (see paragraphs 109–116). The system for the approval of releases into the environment must be made equally sound (see paragraphs 148–153).**

121. European confidence in food technology generally is low. The BSE crisis and outbreaks of *E. coli* 0157 have made the public wary of changes to the food they eat and there is a lack of trust in a little understood regulatory system (Professor Gunter, p 345). **While regulatory judgments should be made solely on the grounds of safety, public attitudes towards genetically modified foods and crops should be accommodated in the operation of the regulatory system. Additionally, however,**

[164] See Professor Bainbridge Q 724.

[165] "Eurobarometer 46.1: the Europeans and Modern Biotechnology": the European Commission, Directorate-General XII (Science, Research and Development). The key findings of the survey are summarised by Professor Durant, pp 312-7.

**public ignorance may mean that the benefits offered by the technology are insufficiently appreciated. Mechanisms must be found for informing consumers about the benefits and risks of genetically modified crops and foods. Exhibitions such as the Science Museum's "Foodfuture" or the BBSRC's[166] "In-gene-ious", excellent though they are, only touch a small percentage of the population. While it is unnecessary for the public to be aware of the details of the regulatory process, they should be able to discover its fundamentals and the process of product development, selection, testing, regulation and monitoring. Thought should be given to the establishment (within the United Kingdom) of a permanent unified information source (see also paragraph 140).**

122. Professor James considered that the establishment of the Food Standards Agency, if sufficiently independent, was an opportunity to attempt to establish, over time, public trust and confidence in food regulation, something which is currently lacking. In the light of the expected timetable, he recommended a "shadow agency", because delay could not be afforded where proper regulation of food safety was at stake (QQ 648, 650, 652–3; also Professor Bainbridge, Q 702). **Internal work in MAFF to prepare for the Agency (Mr Rooker, QQ 613–15) is poor substitute for its launch. We would be encouraged if legislation were to be brought forward in this Session.**

*Public consultation*

123. The Directive proposes to allow public consultation on each application before the competent authority makes its decision. This did not quite satisfy the Consumers' Association, who desired consumer representation, as they have on food committees in the United Kingdom, on the EC advisory committees (Q 146). **We agree that consumer representation should be included on the EC committees, as in the United Kingdom. While complex biological portfolios are unlikely to be of much interest to the general public (and it is to be expected that the majority of comments will be from pressure groups), in the interest of openness, we consider that public comments should be taken into account formally before ACRE makes its recommendation, rather than informally as at present. Government should take account of public opinion (and the public should have the freest access possible to information) but decisions must still be based on sound scientific analysis and the need not to impede scientific progress. (Membership of the United Kingdom's advisory committees is discussed in paragraphs 148–153.)**

*Transparency*

124. Many witnesses called for the approvals process to be open and transparent (for example, Consumers in Europe Group, p 308), although this is already the case in the United Kingdom, but not at Community level. The advisory committees, ACGM, ACNFP and ACRE, have all attempted to place as much as possible of their deliberations in the public domain[167] (Professor Beringer Q 3). All three committees produce comprehensive documentation and annual reports and all have Internet sites[168] which provide detailed information about their activities, including agendas and reports of their meetings. ACRE's site includes summaries of all releases and applications to market GMOs and has attracted about 7,000 visitors during the last year. Applicants are required to advertise their intention to release modified organisms in newspapers widely read in the region of release. Public registers have been instituted so that information relating to releases is nationally available. Information placed in the registers includes summaries of each application to release or market GMOs, the advice ACRE has given to Ministers about the application, the decision, any conditions attached to the permit to release and all monitoring reports which have been required as a condition of the permit. Very few people have examined the registers (41 between 1993 and 1998), but there have been 364 requests for detailed information. **The committees are justifiably concerned that attempts to publicise their roles and to make their scientific assessments available to the general public have not been successful. The advisory committees should continue to place as much information as possible in the public domain. We welcome the Commission's proposal to do the same at Community level and hope that the consideration on the mechanisms to achieve public understanding at Community level will successfully address the need to involve all those using the technology. Transparency, however, must not affect the efficient working of the regulatory committees.**

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166 Biotechnology and Biological Sciences Research Council.

167 Appointments and membership of the committees is considered in paragraphs 148-150.

168 ACGM & ACRE may be found at www.shef.ac.uk/~doe and ACNFP at www.maff.gov.uk/food/novel/acnfp.htm.

*Direct action: the destruction of trial releases*

125. At the United Kingdom level, the openness of the regulators has been exploited by certain groups fundamentally opposed to the technology and committed to preventing its introduction by direct action, such as the destruction of crops on trial release. The NFU argued that nothing will be learnt about the technology if research is continually set back by such acts (Q 292). Mr Meacher stated that "the Government unequivocally condemn the unlawful destruction of GM field trials" but also considered that it would not be right to restrict access to information (Q 626). The chairman of ACRE also did not want to restrict the information it publishes as he considered communication all-important (Professor Beringer, Q 13). **We agree with the Ministers that these actions must be condemned, but we are also opposed to restricting the information made available to the public.**

*Ethics*

126. **As in constructing a regulatory framework (see paragraphs 26–27), the United Kingdom took a lead in assessing the ethics of genetic modification. The reports of the committees chaired by the Rev. Dr Polkinghorne[169] and the Rev. Professor Banner[170] are widely respected. As we have already said, the ethical implications of the technology are being considered by the Nuffield Council on Bioethics and have not been a part of this inquiry. We can however comment on the role of ethics within the regulatory system.**

127. **The regulatory process should only judge products on safety: ethical questions should be addressed before regulation, not during or after. Ethics are culture-related and political, varying between Member States. As it would be unsatisfactory for ethically sensitive products lawfully manufactured and on sale in one Member State to be prevented from being imported into another[171], ethics cannot simply be dealt with by individual Member States. In the same way as agreeing the principles for risk assessment, the Council of Ministers will need to agree on how to deal with potentially ethically sensitive modifications such as the inclusion of animal or fish genes in crops. This must be done at an early stage, preferably in this revision of the Directive, as such modifications will soon arise and where possible the regulations should avoid having to run to keep pace with the technology. The market might be a suitable arbiter. For some people the use of GM products to any extent is an ethical issue.**

*Consumer choice*

128. **Once the regulatory process has ensured safety, the success or failure of the technology must be left to consumer choice in the marketplace. Consumers are justifiably uneasy at the introduction of new technology to their food supply, and especially so when they currently have little option as to whether or not to eat its products, as with the introduction of GM soya and maize. Indeed soya and soya derivatives are present in the majority of processed foods[172]. The consumer has requested and must be provided with the choice as to whether or not to eat GM foods.** The two issues involved in providing choice are the supply of GM and non-GM products and labelling.

*Segregation or identity preservation?*

129. Whether GM crops and products should be segregated from their unmodified alternatives throughout the food supply chain is a contentious issue. The arguments in favour of compulsory segregation rest on consumer and market choice. The consumer is not just the shopper in the supermarket: manufacturers such as the Scotch Whisky Association advocated segregation to enable them to choose more easily whether to use GM raw materials (pp 389–90). It is not a novel idea: some commodity crops such as wheat and rice are already segregated for their properties. Segregation is not

[169] Report of the committee on the ethics of genetic modification and food use, HMSO 1993.

[170] Report of the committee to consider the ethical implications of emerging technologies in the breeding of farm animals, HMSO 1995.

[171] In the *Cassis de Dijon* case (Case 120/78, Rewe-Zentrale AG v Bundesmonopolverwaltung fur Branntwein [1979] ECR 649) the Court of Justice established the principle that goods lawfully produced and marketed in one Member State should be admitted into any other Member State without restriction. The Court also recognised however that obstacles to the free movement of goods could be justified if necessary to satisfy "mandatory requirements". These might relate to the effectiveness of fiscal supervision, protection of public health, fairness of commercial transactions or consumer protection. As regards consumer protection the Court has, as a general rule, considered appropriate product labelling to be a sufficient safeguard.

[172] Approximately 60 per cent.

necessarily to the detriment of the technology. Indeed Safeway argued that consumer opposition to biotechnology had been increased by the lack of first wave segregation, which compromised consumer choice (pp 84–5). The commercial success of the Zeneca / Safeway tomato paste has shown that GM can compete when marketed side-by-side with an unmodified product.

130. On the other hand, once a product has been judged to be safe, there seems little reason to require it to be treated differently from the unmodified alternative. The practicalities of commodity crop farming have also to be considered. For American soya, harvesting happens quickly and crop from miles around is processed via bulk elevators with no regard to its origin or type. Segregation would also require independent supply and processing lines (United Biscuits, Q 578; Mr Rooker, Q 618).

131. **It may be too late to recommend the segregation of soya and maize, not due to any burden this might place on the United States' production line, but because US farmers have taken up the technology so rapidly that the majority of the crop will shortly be modified (American Soybean Association, p 295). European Community and American farmers should realise that there is a potentially lucrative EC market for unmodified commodity crops. Ultimately however, market economics will effectively produce segregation, perhaps based on zoning, as value added products[173] are introduced. Farmers will separate their crops because each will have a different asset and value.**

132. **Segregation must be driven by the market and not required by Government, as acknowledged by the manufacturers and Ministers (FDF Q 552, Mr Rooker Q 616). Producers and manufacturers should however be under no illusion as to the climate of consumer opinion in Europe and it would be advisable for the immediate future, as genetically modified products are first brought to market, for segregation to occur to facilitate consumer choice. At this stage of the development of the technology, we are persuaded that segregation will play an important part in rebuilding public confidence. We support, as did the Ministers (Q 605), the segregation of crops when on the farm, their segregation at harvest and full labelling of the harvested crop. Whether segregation should be continued beyond this point is a matter in dispute.**

133. The market-driven alternative to mandatory segregation is often described as "identity preservation"[174]. This has been developed by companies such as Iceland, Spillers and United Biscuits[175] (QQ 163–71, 567, 578). The system depends on securing a supply of unmodified crop by ordering it from a farmer before it is sown and controlling it until it reaches the food factory. While the process requires additional effort, it respects both market forces and consumer choice. The Government have been involved by helping to identify sources of unmodified crops (Q 616) and have so far identified 59 suppliers of unmodified soya in north America[176]. **The identity preservation system is to be commended, but it is however only a means of acquiring the ingredients. The crop and product must still be subject to the standard testing and labelling regimes as GM material has often been found in supposedly unmodified shipments (see paragraph 141).**

134. **The segregation or identity preservation of commodity crops will not result in modified and un-modified products on sale side by side at the same price, but will result in "GM free" products available at a premium price, similar to organic produce.** (The FDF suggested the premium would be 40 per cent., whereas United Biscuits' current suppliers of unmodified crops charge a 10–15 per cent. premium (QQ 555, 580).) The raw ingredients however represent only a small element of the cost to the consumer.

*Labelling*

*—Why label?*

135. Under United States regulations, once certain GM products have been cleared by the regulatory process they need not be identified to the consumer: "You do not label GM tomato paste? / It is just tomato paste."[177] (Q 387). Many GM foods are absolutely identical to their unmodified

[173] For example, soya with enhanced oil properties or vine-ripened tomatoes with delayed ripening / rotting.

[174] Often confused with traceability.

[175] United Biscuits have opted for this route as they are aware of a market for unmodified foods due to current consumer uneasiness (Q 567).

[176] HC Deb., 12 November 1998, col. 471.

[177] Question to Mr Galvin of the USDA and Mr Galvin's response.

equivalents[178] (see paragraph 109). The United States' approach is also based on the belief that, even were the product labelled as GM, the consumer would not be able to make a rational choice based on that information. They consider that the information that a product is genetically modified is not in itself information useful to the consumer, as the consumer is not aware of the working of the technology or of other aspects of their food supply. In this country, however, the major retailers, manufacturers and consumer groups are all convinced that labelling is of primary importance (CA, p 52; CEG, pp 308–9; CWS, p 311; Safeway, p 85; NFU, p 99; FDF, p 333). J Sainsbury's policy for example is that genetically modified food should be labelled to allow informed choice (pp 387–8). Labelling is also advocated so that those opposed to the technology (as against eating food derived from it) may choose not to use it (CWS, p 311). Labels should be "understandable, truthful and not misleading" (Canadian High Commission, p 299) or "clear, honest and neutral" (Austrian Embassy p 297, see also FDF Q 548). Professor Durant suggested that the reason for lack of public support for GMOs is that they are not yet seen as particularly useful: public support will only come when the foods are shown to "possess clear and demonstrable consumer benefits" (p 312). Labelling would help to identify these benefits as products become available (p 313). **The United States' approach is not likely to be accepted by European consumers for the foreseeable future. We welcome the requirement in the proposed revision of the Directive for explicit labelling of GM products in order to help provide consumer choice[179]. It is right to provide choice through labelling at this early stage of the introduction of a new technology. The requirement for labelling should however be reviewed in the light of consumer preferences expressed in a changing marketplace. Labelling should not be statutory for anything other than food.**

*—Label what?*

136. As a result of three major consultations, the Canadian government has required that novel foods derived from GMOs must be labelled only to identify the presence of potential health or safety risks for individuals and where there are significant changes to the composition or nutritional value when compared to the non-engineered food. If there are no such changes, then labels are not required (p 299). This is also the approach in the United States. **While this would hopefully be appropriate for the EC at some stage in the future, a more inclusive policy is required at present.**

137. The Commission's proposal to label where the transgene or its product is present but not otherwise drew criticism as a step back from "labelling for process", which would allow consumer choice based on opposition to the technology *per se* (CWS, p 311). The logic of the Commission's position is that where chemicals produced in novel organisms are identical to chemicals produced by other means they should not require labelling (USDA, Q 387). For example, an oil refined from herbicide tolerant soya should contain neither genes nor gene products, would therefore be identical to oil from un-modified soya and so would not require labelling. There is however, as of yet, no common list of products exempt (for these reasons) from labelling[180]. **To require labelling for process in this field (as opposed to its use as a marketing tool, for example for free-range or organic produce) should logically necessitate labelling for process for all foods, identifying for example what fertilisers, pesticides, herbicides, preservatives and stabilisers were used in the production of an ingredient or product, a suggestion which in practice is not feasible. We agree with the Commission and Government (Q 617) that only products where the transgene or its product are detectable should be labelled. To demand labelling where such detection is impossible would be meaningless. It would also, wrongly, imply traceability (see paragraph 117). However, a Community list of products which do not require labelling is urgently required.**

138. **Any ingredient or additive to a product should thus be identified as GM[181] when the presence of GM material can be detected above an established threshold (see paragraphs 141–142). No labelling would be required below the threshold. Additionally, if a finished product contains GM material above a threshold the product itself should be labelled[182]. Any manufacturer wishing to claim "GM free" must be able to prove that claim by testing, and if**

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178 For example tomato paste or sugar.

179 The exact proposals for labelling which currently appear in Annex 4 of the draft Directive require alteration to comply with the compromise achieved in Council Regulation (EC) 1139/98. The regulation requires that all foods which contain genes or gene products from GM maize or soya must be labelled to that effect. It is important that the regulation be generalised to cover all foods derived from genetically modified organisms.

180 Termed the "negative list".

181 By means, for example, of an asterisk next to the GM ingredient in the ingredients list and an explanation at the end of the list along the lines of "* = a product of genetic modification".

182 By stating "Contains the products of genetic modification." at the beginning of the ingredients list.

**testing is not possible, then by audit trail (see paragraph 131 below and FDF Q 556). No potentially allergenic or ethically sensitive modifications[183] have yet been presented for approval, but labelling of any such cases will need to be more explicit (see paragraphs 126–127).**

139. **The above policy is easily implemented for packaged foods which already bear detailed labels. Unpackaged foods and restaurants present a special problem[184].**

*Enabling informed choice*

140. Professor Bainbridge illustrated the level of consumer understanding of labels with the example of energy values. Consumers are often keen to know whether or not a food will make them fat and thus examine food labels for Calorie levels. The current SI[185] unit is however the kilojoule, not the kilocalorie, and the information is thus not understood (Q 722). **Mr Galvin of the USDA was indeed correct to say that the bald label "genetically modified" or an equivalent is virtually meaningless to the average consumer (see paragraph 135). It is impossible to convey the necessary information to allow informed choice on a product label. Supplementary information must thus be available to the consumer. Though retailers are attempting to provide some information (J Sainsbury, p 389) and manufacturers have equipped their "carelines" to deal with GM-related calls (United Biscuits, Q 573), the information a single company can provide is understandably not of the comprehensive nature to which consumers should be entitled. We recommend that Member State governments co-ordinate (but not necessarily be responsible for) the establishment within each State of a source of information regarding GM foods, to which the consumer may resort for information not provided on the product label** (supported by the FDF (Q 549) and more cautiously by United Biscuits (Q 574)) (see also paragraph 121). **Retailers, manufacturers, developers, environmentalists and regulators should be involved. As well as providing accurate and comprehensive information, such a resource may also assist with improving public confidence in the technology and its regulation. This should as soon as possible fall under the remit of the proposed Food Standards Agency.**

*Testing and thresholds*

141. A labelling policy requires a testing policy in order to establish the accuracy of the "contains GM" labelling (or the absence of such labelling) and so provide honest and accurate information to the consumer. This is even the case with segregated or identity preserved (see paragraphs 129–134) ingredients, as demonstrated to us by United Biscuits, who have found up to 1.5 per cent. GM product in supposedly unmodified shipments (Q 567; FDF, Q 554). LGC (formerly the Laboratory of the Government Chemist) has researched the issue of testing for MAFF and, while there are still questions to be answered[186], testing seems both possible and practicable (pp 358–66). Validated quantitative tests need to be developed ("at present these could be considered semi-quantitative" (p 358)) and thresholds[187] need to be agreed across the Community. **The absence of a testing and thresholds policy is a serious gap in current European and domestic legislation (FDF QQ 554–8; United Biscuits, p 400), leading to confusion and varying standards amongst manufacturers and inaccurate information for consumers. We recommend that MAFF should issue interim guidelines until a Community policy is agreed, which may not be for several years.**

142. The primary threshold called for is a *de minimis* threshold, whereby GM presence below the threshold would not require the ingredient or product to be labelled (United Biscuits, Q 567; FDF, Q 554). The threshold for organic products is 5 per cent. non-organic[188] and for durum wheat is 3 per cent. (Mr Rooker, Q 618). **The detectable limit for GM is currently 0.1 per cent., A workable but cautious threshold for GM presence in an ingredient would perhaps be 2 per cent., less than half the level which applies to organic products. This threshold on its own would however result in an anomaly which would mislead consumers, whereby an unlabelled product using a lot of an ingredient below the threshold may actually contain more GM material than a labelled product**

183 Such as a vegetable containing genes copied from an animal.

184 See, *inter alia*, Professor Bainbridge, Q 720.

185 *Système International* – the international system of units of measurement.

186 Such as sampling frequency.

187 Thresholds determine the percentage "purity" above which a sample is, for example, considered to be unmodified.

188 Council Regulation (EEC) No. 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs, Article 5 (OJ L198 (22 July 1991) pp 1-15).

**containing only a little of the GM ingredient[189]. The same threshold of 2 per cent. must thus also be set for labelling the end product to prevent this anomaly. This will not require all finished products to be tested as the calculation of GM presence in the end product can be made arithmetically if the level of GM presence in the ingredients is known, as it will be from the test result.**

143. **Soya and maize however present a special case due to the uptake of the technology in the Americas. Where soya and maize are concerned, testing should not be required but the ingredient should be automatically labelled as genetically modified. If a retailer should wish not to label, or to market as non-GM, then the ingredient would have to be tested. In our opinion, it would not be sufficient to rely on the supplier's word[190].**

144. **Testing procedures are constantly developing and the extent to which it will be possible to detect genes or proteins in refined products is likely to increase. Therefore a product which currently does not require labelling may subsequently have to be labelled in order to comply with the regulation.**

*Labelling: conclusion*

145. **We consider that the recommendations above present the best achievable situation, although we recognise that some of our witnesses would have preferred labelling for process. In our view this would be impractical. The worst aspect of the present situation is that there is but a partly-developed policy. For example, the "negative list" is not expected to be published before the end of 1999 (see paragraph 137). If a European strategy is not to be agreed for several years, the Government should introduce its own regulations as swiftly as possible to end manufacturers' confusion and the current misleading of consumers. Labelling, segregation and testing policies should all be reviewed as the technology develops. As GM products become more commonplace, it is also possible that the consumer may cease to demand special treatment for the fruits of the technology.**

REGULATION

146. In 1993 the House of Lords' Select Committee on Science and Technology reported on the regulation of biotechnology[191] in general. Their report concluded that regulation should be kept to a minimum:

> "the benefits of biotechnology are already well proven; biotechnology and products of biotechnology are with us to stay; and these products will yield enormous future benefits to mankind. What is more, United Kingdom scientists and industry are good at it. We think that in all areas where biotechnology has applications, people should be able to exploit its economic benefits, subject only to such regulation as may be necessary to meet identifiable disbenefits, especially to preserve safety."[192]

147. The Science and Technology Committee's report was written when virtually no genetically modified organisms had been intentionally released into the environment and there had been no application to release on a commercial scale. To date only a small number of products have been approved for commercial release within the European Community (see Appendix 4[193]),

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189 For example, soya supply X contains more than 2 per cent. GM material and so requires labelling if used in a food product. Soya supply Y has been "identity preserved" and contains only 0.5 per cent. GM material and thus does not require labelling. If soya Y is used to make something predominantly consisting of soya (For example when used as a meat substitute in vegetarian products) (product A) and soya X to make something using only a trace amount (product B), product B would be labelled but product A would not, even though A contains far more GM material than B.

190 This is especially the case with Brazilian soya, where many farmers grow seeds, possibly GM, purchased from the US when the Brazilian government has yet to approve the commercial release of GM crops.

191 Science and Technology Committee, 7th Report (1992-93): *Regulation of the United Kingdom Biotechnology Industry and Global Competitiveness* (HL 80).

192 Ibid., para. 1.3.

193 See also the memorandum by the DETR, p 192.

compared with a great many in the United States[194], but the commercial exploitation of genetically modified maize, soya and cotton in the United States and Canada[195] has meant that world production is now significant[196]. More than 60 per cent. of processed foods sold in supermarkets contain soya, most of which comes from North America and may therefore contain a significant proportion of the genetically modified produce. **We agree that regulation should be kept to the necessary minimum, but the release into the environment and food use of GMOs require strict regulation.**

*United Kingdom regulatory committees*

*—Membership*

148. While ACRE (see paragraph 32) received compliments from our witnesses[197], its membership was criticised by Iceland (p 62) and Greenpeace (Q 103) as being dominated by those connected to, knowledgeable about or favourable towards the technology and some have called for membership to be broadened to include consumer representatives. **ACRE's role is to assess the safety of complex products based on complex data. As a result, the membership of such a regulatory committee must be dependent on scientists. Some of those competent to assess the data are inevitably going to have a degree of connection to the agro-chemical/seeds sector[198]. We do not question ACRE's integrity, but it and its members must be seen to be acting independently. We were informed that when an application is submitted to which a member is commercially connected, that member leaves the room while it is discussed and plays no part in the decision-making (the same is true of ACNFP (Mr Rooker, Q 624)). The membership of such a committee should however be balanced in its expertise and we value Mr Meacher's commitment to broaden it in ACRE's case[199] (Q 607), particularly given the wider environmental remit we recommend in the next paragraph. The consumer representation on and contribution to ACNFP is much valued by all involved[200]. We believe the same would work in ACRE's case and that its membership should thus include a consumer representative. In the interests of openness, it is also right that there should be a rotation in the membership of such committees. It is desirable however that a body of knowledge should be built up. That which ACRE has acquired may be lost when ten of the current 13 members retire in April 1999 as expected (Mr Meacher, Q 613). We would very much regret such a lack of continuity and would urge the Government to review the situation as a matter of urgency. This position should be avoided in future.**

*—Role*

149. Several witnesses criticised the narrowness of particularly ACRE's remit, whereby it is unable to take all of the pertinent issues into account (Greenpeace, Q 103; Green Alliance Q 195; SNCAs, p 322; CA, p 53, Mr Meacher, Q 607). **The remit of ACRE should be adjusted so that it considers, for example, indirect and cumulative environmental effects when judging individual applications (see paragraphs 89–95).**

150. The actual role of ACRE and ACNFP can also be questioned. In the United States, the government conducts the risk assessment. Some countries outside the EC have adopted this approach, whereby the same officials make decisions on the information needed to support the assessment and on the assessment itself. The United Kingdom (and EC) system has introduced the concept of scientific audit. The advisory committee assesses whether the information supplied by the applicant is adequate and whether the assessment is accurate. The committees often request further information and research before reaching a decision. **We consider that the United Kingdom's audit approach is**

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194 Including varieties of maize, oilseed rape, tomato, cotton, potato, soybean, squash, chicory and papaya.

195 China is also considered to be using GM crops on a large scale.

196 Monsanto projects (p 140) that over 10 million hectares of genetically modified soybeans, involving about 300 new varieties will be cultivated in the United States in 1998 (approximately 30 per cent. of the total soybean acreage) and a further 4 million hectares of soybean will be grown in Argentina.

197 Safeway, p 85; Nestlé, p 367; United Biscuits, p 404; Zeneca Q 72.

198 Especially when private funds are the primary source of research funding. Professor Bainbridge suggested that, in some aspects, the research and development sections of the biotechnology companies were arguably in advance of the leading universities (Q 694).

199 Some have suggested that some areas of expertise are lacking at present, for example, ecotoxicological knowledge.

200 See paragraph 152.

**valuable and not inferior to the alternative of assessment by government officials. Accordingly we support the *status quo*.**

*—Strategy*

151. A distinction can be drawn between the scientific assessment of individual applications for release (performed by ACRE) and a strategic examination of the issues relating to genetic modification. There have been increasing calls for a new committee of some sort. Professor James called for an ability to take a broad view, especially as the number of individual applications for releases increases (Q 671, also Professor Bainbridge, QQ 681, 692) – otherwise we will be in danger of losing sight of the wood for the trees. Mr Meacher announced to us that he is considering calls to establish an "environmental stakeholders' forum" (Q608) and the Royal Society have recently called for an "over-arching" committee[201]. Both are aimed at what Mr Rooker referred to as "joined up government" (Q 606). **To this end we can but welcome the establishment of the cabinet committee[202] under the Minister for the Cabinet Office (Dr Cunningham). We consider however that a new committee is still required because a more detailed and continuous approach is necessary. Which of the two options to choose, forum or over-arching, depends on the remit necessary to achieve the strategic end.**

152. **We believe that a new committee is needed to examine more general issues which arise from the use of genetic modification in agriculture and to co-ordinate and plan policy as a "seamless whole" (FDF, Q 544), as opposed to the assessment of individual applications which should continue to be performed by ACRE. Such a committee is needed to address predominantly environmental[203] questions raised by the current advisory committees which either fall outside their remit, or which require an integrated response from Government, for example the regulation and monitoring of herbicide tolerant crops. The remit should include the impact on agriculture in general of the integrated management of novel crop plants and their cumulative effect, changes to agricultural practice and changes in pest control and herbicide use (see paragraphs 94–95 and 105–106). The committee would need to ensure that appropriate research was conducted and acted upon. The committee should have issues referred to it by Ministers or ACRE but should also act on its own initiative. It should seek advice from the other advisory (and regulatory) committees and vice versa. It should establish the principles by which the development and application of the technology should proceed. Its membership should be wide-ranging (including cross-membership with other committees) and we believe that the committee would be effective with consumer representatives involved. These issues are not solely the preserve of scientists, as has been demonstrated by successful consumer involvement in the food regulatory committees** (Professor James QQ 648–9; Professor Bainbridge, Q 688).

153. **The remit we envisage necessitates a committee similar to that proposed by the Royal Society rather than a stakeholders' forum. It would appear that the latter would be but a forum for debate whereas we wish to see a more integrated approach to policy. For example, it is good that Mr Rooker has commissioned an analysis and comparison of herbicide tolerant crops (see paragraph 68), but this sort of research and analysis should not be dependent on occasional Ministerial attention but be able to be commissioned and acted upon by the new committee. The committee should engage in broad consultation with interested groups.**

*Filling gaps in the system*

154. **It is distressing to find that regulations have been and are still running to keep up with the technology. This is confusing for those involved and a reason for consumer disquiet. We still lack a Community labelling policy (United Biscuits, p 400). The revision of Directive 90/220/EEC offers an opportunity to try to create more durable legislation. Gaps not already identified include:**

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201 Op. cit., p 13.

202 The membership of the ministerial group on biotechnology and genetic modification comprises the Chancellor of the Duchy of Lancaster and Minister for the Cabinet Office (Chairman); the Minister of State, Department of the Environment, Transport and the Regions; the Financial Secretary to the Treasury; the Minister of State, Foreign and Commonwealth Affairs; the Minister of State, Home Office; the Minister of State, Cabinet Office; the Minister of State, Department of Health; the Minister of State, Ministry of Agriculture, Fisheries and Food; the Minister of State, Department of Trade and Industry; the Parliamentary Secretary, Cabinet Office; and the Parliamentary Under-secretary of State, Department of Trade and Industry. The Chief Scientific Adviser also attends.

203 Food issues should be dealt with by the Food Standards Agency.

*—Animals*

155. **GM animals will primarily be used in containment and, unless they escape, as such do not pose release problems. The possibility of accidental release, escape and cross border transfer is not yet covered by Community legislation.**

*—Fish*

156. **Fish are being modified for rapid growth and cold tolerance[204] and further modifications are in development. Once released, it would be impossible to recapture a fish or to control its breeding (unless sterile). Fish do not respect national boundaries and we would be very concerned if sea or river releases were to take place here or abroad. We strongly recommend that there be an international agreement prohibiting such actions. Any trials or commercialisation must be in containment and not released into the sea or freshwater network.**

*—Release - whose decision?*

157. **In certain cases, particularly for animals, there is no need to notify a competent authority of the environmental risk assessment if the user decides that an application of the technology is contained. We consider that the decision as to whether or not a use of a GMO is a release should be subject to review by the competent authority.**

*—Imported food*

158. **The EC's current control regime for GMOs has given rise to some difficulty between United States manufacturers and the EC regulatory authorities[205]. The process could be assisted if, where there is no intention to use an imported product other than in food or feed (i.e. not for growing), the risk management procedures were to focus mainly on the properties which affect human or animal health and safety. The permit should specify the procedures needed to ensure that the product cannot be grown and reproduced. If the product can be grown (as with soya beans but not with soya oil), an assessment of the risk to the environment would have to be performed and risk management would need to be implemented to avoid release. It is important to note that consents to market GM foods are valid throughout the EC and the Commission should take steps to ensure that these consents are permitted to operate in every Member State.**

*EC efficiency*

159. **The safety and public concern considerations outlined above justify that effort should be put into the regulation of GMOs. The process must however be conducted effectively and efficiently and subject to review in the light of experience.**

*—Politicisation and opt-outs*

160. **As Europe has a single market it is right that the approval procedure for commercial releases should be European. The procedure involves all 15 Member States and results in a Community-wide permit to grow and market a crop. The regulatory process is meant to be exclusively scientific, but the domestic pressures of Member States have intruded and caused delay. This might be assisted if a degree of opt-out for growing was available[206]. We acknowledge that domestic pressures, ecological and agricultural conditions vary across the Community and consider that Member States should have the right to opt-out of growing certain GM crops for domestic or environmental reasons (i.e., after approval, a Member State could disallow commercial release within its territory). We acknowledge that this will hinder the single market in seeds (HMG officials, Q 483), but consider this preferable to the Community being forced to proceed at the pace of the most reluctant. The products of such crops, food or other, should however be available throughout the Community and the market will determine their acceptability and so success or failure.**

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[204] HSE, pp 350-1.

[205] The EC requires each novel food to be assessed and approved before it can be imported into the Community. This process is holding back shipments of several commodity crops which the United States had expected to be able to sell to Europe.

[206] As may be desired for example by Austria, France and Luxembourg.

*—Alteration of the release procedures*

161. **We note and share the concern expressed by DETR (Q 437) at the removal of the current simplified procedures for trial releases. The introduction of two levels of release, the first of which is considered relatively without risk, does not adequately replace the current procedure. If the *status quo* is not to be maintained then the new provisions need clarification to prevent discrepancies of interpretation between Member States. We do not consider attractive the proposal whereby research and development releases in several Member States would be processed initially at Commission level before being passed to each Member State for decision. The new procedure would be less efficient than the current system which requires a separate application to the Competent Authority in each Member State. We do, however, support the proposal for simplified permits for repeat experiments. We support the Commission's forward planning whereby a simplified procedure for marketing applications is established.**

*—Comitology*

162. The current comitology procedure appears to allow applications to succeed when most Member States are opposed. We therefore support the proposal to move from the IIIa to the tighter IIIb procedure (see paragraphs 59–60). Under this procedure, a simple majority of Member States may prevent a product being marketed, an option not available under the IIIa procedure. This should not allow products on to the market when a majority of Member States have been opposed (as has seemed to happen under IIIa).

*—Community scientific advice*

163. The proposed revision of the Directive formalises a requirement for the Commission to consult its scientific committees[207] when a dispute has arisen between Member States. Professor James, a senior member of the scientific steering committee and Dr Chesson, a member of the GMO committee, described a convoluted process for appointing members to the committees, ostensibly with regard to expertise but inevitably with careful reference to geographic distribution. Of more concern was the use of inappropriate expertise: Professor James found himself responsible for a cosmetics committee (Q 654). Community science is more frequently criticised for its operation than for the quality of its advice, and this assessment was confirmed by Professor James and Dr Chesson (Q 658). Though the position had improved now that Directorate-General XXIV was responsible for all the committees, too much pressure was put on academics giving their time voluntarily (QQ 656, 661, 668). There was not sufficient scientifically literate administrative support at Community level. The support was estimated to be between a quarter and a tenth of the level a similar committee in a Member State would receive (Q 655). These two factors had led to the resignation of some British academics. Some Member State governments provided up to ten staff for their nationals on these committees to assist with the workload (Q 656). Professor James commented that the "pressure of the last year has been too intense to get really very well balanced, beautiful judgments that are explicit and clear in all aspects." (Q 658). In addition, the committees were often asked by the Commission to comment on an issue without sufficient background information (Q 660). The committees' time was wasted when essentially political issues were referred to them (Q 659). Perhaps more seriously, the interlocking of the committees and sub-committees was too muddled, with the result that issues could fall between committees (Q 655).

164. **We consider that consultation of the scientific committees will be useful for resolving inter-Member State disputes. The appointment, membership and operation of the committees must be open to scrutiny. The current method of appointment is inadequate. Appointment must be on the basis of scientific expertise and should not necessarily reflect geographic considerations or the voting strengths of Member States. The structure of the committees could also be streamlined to increase their relevance to the regulation of GM releases. The committees require improved resources in Brussels. It is not appropriate for Member States to support their nationals as the members of the committees are independent academics not representatives of Member States** (Q 657). **The committees need relevant, precise questions put to them by the Commission at the earliest possible stage with the fullest information available. While it is necessary for the committees to be able to take a broad view when examining an issue, they should only be required to comment on the specific disputes between Member States and should not be required to re-assess dossiers from scratch, especially as each dossier will already have been examined in detail by the lead Member State's scientific committees and also by every other Member State** (Professor James, Q 667).

[207] Those operating under Directorate-General XXIV.

165. Professor James and Dr Chesson approved of stopping the clock[208] (see paragraphs 63 and 167) for the committees' consultation, primarily as a vast amount of information had to be assimilated by academics giving voluntarily of their time. They admitted however that this might not be necessary if the consultation was more efficient (QQ 662–3). **We consider that the efficiency of the committees' working should be improved before resorting to stopping the clock. If this proves impossible, consideration will need to be given as to whether it would be preferable to make the committees permanent or to stop the clock.**

*—Time limits*

166. The delay inherent in the European regulatory system (the stages of which are described in paragraphs 61–63) attracted repeated criticism, including Mr Meacher, who referred to "unjustifiably long delays at a number of stages" (Q 621). Professor Beringer commented that it was the "regulatory environment in Europe which is a major stumbling block". He described a "very weak, ineffectual and (I would even use the word) incompetent system in Brussels which is allowing various delaying tactics to be introduced" (Q 20). Monsanto noted that the approximate average time from the initial submission to the lead Member State to publication of the approval in the Official Journal is 18–19 months, whereas in the United States it is 7 months (pp 137–8)[209]. **This is a major problem which must adversely affect Europe's competitiveness. The unnecessary delay in approving products has created a vacuum in which ignorance has been exploited and the consumer is both denied choice and the opportunity to build up experience.**

167. The industry's call was not so much for a speedy system but for a predictable system (Zeneca, p 21). Research and commercialisation programmes are not conducted on a whim and demand accurate funding and planning. The United States argued that consultation of the Community scientific committee should not have been arbitrarily introduced into the working of the current system, whatever its merits (p 155) and Dr von Schomberg and the DETR noted inconsistency in the application of risk assessments between Member States (p 404; Q 439). **We thus welcome the introduction of strict time limits and the definition of risk assessment which should help end discrepancies between Member States. There are however two flaws. The first is too ready a willingness to stop the clock. We recommend that the clock should only be stopped when further information is requested from the applicant. Additionally, the Commission has failed to set itself a time limit for approving or rejecting a release following the (in)decision of the Council. Almost all of the applications that have so far been considered have been delayed by the Commission, and of the four applications submitted in 1995 only two had received consent by June this year (DETR, pp 187–8). This stage should be automatic or subject to a token period of a week. So should the subsequent issuing of a permit by the lead Member State, following EC approval.**

168. **It will be a considerable period of time before the revision of the deliberate release Directive is adopted, especially as the European Parliament is involved under the co-decision procedure. We thus urge the Commission to reform its internal workings so that the present system is subject to less delay. Member States should agree voluntary time-limits where they are currently not set under the existing Directive.**

169. Monsanto complained that the two-year national plant variety registration system[210] placed an unnecessary additional hurdle at the end of an already protracted process. **The committee recognises their frustration, particularly where trials have been performed which meet the same criteria, and consider that the results of such trials should be acceptable for plant variety registration.**

*—Seven year consents*

170. The draft Directive proposes that marketing consents be issued for seven year periods and only renewed for seven years at a time. While supported by some, such as Iceland (p 355), this proposal has drawn much criticism (Professor Beringer Q 443; DETR Q 443) and **we find no merit in it. There is merit in imposing valid conditions on individual applications for consent and in**

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208 A term used to indicate suspension of a time limit.

209 The USDA rules for submission of dossiers (7CFR340.4b, for example) notes that the 120 day review period for applications only starts when a valid and complete application is received. In Europe the time starts on receipt of a dossier, although the "clock may be stopped" if additional information is requested.

210 The Community plant variety rights system is implemented through Council Regulation 2100/94 and implements the International Convention for the Protection of New Varieties of Plants (UPOV). It applies to all new varieties, and requires testing for novelty, distinctness, uniformity and stability. In the United States the plant patent system is used in preference to the registration system.

**placing a time limit on a product for which there is a particular concern (see paragraphs 100–101). It is also important that permits may be withdrawn at any time if there is evidence of harm to the environment or to health. If monitoring is conducted properly, if a report on any unexpected events or harm to the environment is required and if the permit can be revoked at any time should evidence of harm arise then the specification of a time limit is pointless. The same proposal implies that permission will only be given for a specific product as opposed to a class of products. This could cause severe difficulties to plant breeders who would want to create a number of varieties in order to maintain agricultural biodiversity, decrease susceptibility to disease and to ensure that it is the best varieties that have modified characteristics.**

COMPETITIVENESS

171. The agricultural and food use of biotechnology is already well established in other major OECD countries such as the United States and Canada and in major food producing countries such as Argentina and China. **Any undue delay, cost or burden in Europe will jeopardise the competitive and productive position of our scientific, agricultural, manufacturing and retail industries (John Innes, p 358) and hence employment. It may also improperly restrict future scientific developments. It will also unnecessarily deny consumers access to the products of the technology. GMOs need to be regulated, at least until our knowledge develops further, but it would be extremely damaging if Europe's access to this technology was subjected to inappropriate impediments.**

## PART 4: SUMMARY OF CONCLUSIONS AND RECOMMENDATIONS

### POTENTIAL BENEFITS AND RISKS

172. Biotechnology in general and genetic modification in particular offer great potential benefits to agriculture, industry, consumers and even to the environment. We consider that GM technology may offer much to organic systems, for example through reduced inputs (paragraphs 65–72, 78).

173. There are potential risks relating to the environment, including the impact on ecosystems of out-crossing, pest resistance and stress and multiple tolerances (paragraphs 73–86).

174. We consider that environmental risks and benefits should be assessed at the same time (paragraphs 87–88).

### RISK ASSESSMENT

175. The risks involved in genetic modification can, we believe, be controlled, if a strict risk management process is in place. A clear, coherent set of principles for environmental impact analysis is needed which allows for consistent interpretation by Member States (paragraphs 89, 92–93).

176. We recommend that risk assessment should include direct, indirect, immediate and delayed effects. The regulatory system should attempt to predict interactions. A system which attempted to identify an integrated approach would be preferable to what amounts to a first come, first served approach (paragraphs 94–95).

177. In assessing risk, we recommend that modified plants and their management schedules should be compared with the use of a similar non-modified crop and best agricultural practice (paragraph 90).

178. We recommend that there should be triggers other than genetic modification which bring the assessment and management system into action, as is the case for novel foods. We recommend that, from now on, any crop with novel traits which may have the potential to impact significantly on the environment should be subject to an oversight system (paragraph 91).

179. The knowledge of how a crop grown on farm and commercial scales will interact with the environment can only be acquired by growing it on such scales. Large scale trials are needed. We consider that an outright moratorium would be inappropriate (paragraphs 96–99).

### RISK MANAGEMENT

180. We welcome the ability to set specific conditions for each commercial release. We are however concerned that the draft Directive does not envisage an end-point at which the GM crop is considered safe enough to be released into the environment without such constraints (though perhaps with certain management conditions) (paragraphs 100–101, 170).

181. Conditions and regulations should only be imposed where necessary, but must be adhered to when imposed. The general conditions may best be established through a (preferably pan-European) government-sponsored code of practice. It may be the case in this instance that a voluntary code of practice will not be sufficient; if so, the code of practice should be backed up by regulation (paragraphs 105–107).

182. Monitoring is not a substitute for risk assessment but can complement it. We consider that those involved should report on any predicted effects which do not occur and any unexpected events which do occur. We recommend that monitoring (to Community-wide standards) should be performed by an independent organisation, funded through levies on applicants. There must also be a Community-wide audit of enforcement as monitoring standards (in many fields) have in the past been subject to too great a variation (paragraphs 102–104).

### GM FOOD

183. We consider the regulatory process for assessing the safety of novel foods to be thorough and proper and we see no reason to doubt the safety of foods which have been approved by the regulatory process. The emphasis should not be on "genetically modified" but on the new characteristics of any individual product (paragraphs 109–116).

184. Antibiotic-resistant marker genes should be phased out as swiftly as possible. Research needs to be conducted into how best to consider applications involving genes without proven track

records of food use. We support the call for the accumulation and sharing of national data to assist regulators (paragraphs 75, 109–116).

185. Internal work at MAFF to prepare for the Food Standards Agency is poor substitute for its launch. We would be encouraged if legislation were to be brought forward in this Session (paragraphs 118–122).

186. Genetic modification does not concern a single product or variety but will soon affect the whole spectrum of agriculture. To require traceability for all agricultural commodities would be an exceedingly costly exercise for little benefit, especially when there is no anticipated risk to human health (paragraph 117).

### Consumer choice

187. Once the regulatory process has ensured safety, the success or failure of the technology must be left to consumer choice in the marketplace. The two issues involved in providing choice are the supply of GM and non-GM products and labelling (paragraph 128).

188. Segregation must be driven by the market and not required by Government. Producers and manufacturers should however be under no illusion as to the climate of consumer opinion in Europe and it would be advisable for the immediate future for segregation to occur to facilitate consumer choice. The identity preservation system is to be commended. The crop and product must still be subject to the standard testing and labelling regimes as GM material has often been found in supposedly unmodified shipments (paragraphs 129–134).

189. We welcome the requirement for the explicit labelling of GM products in order to help provide consumer choice. We agree with the Commission and Government that only products where the transgene or its product are detectable should be labelled. To demand labelling where such detection is impossible would be meaningless. A Community list of products which do not require labelling is urgently required (paragraphs 135–139, 145).

190. Any ingredient or additive to a product should be identified as GM when the presence of GM material can be detected above an established threshold. No labelling should be required below the threshold. Additionally, if a finished product contains GM material above a threshold the product itself should be labelled.

191. The absence of a testing and thresholds policy is a serious gap in current European and domestic legislation. Until a Community policy is agreed we recommend that MAFF should issue interim guidelines. A workable but cautious threshold for GM presence would perhaps be 2 per cent. (paragraphs 136–139, 141–144).

192. Information supplementary to that provided on the label of GM foods must be available to the consumer. We recommend that Member State governments co-ordinate (but not necessarily be responsible for) the establishment within each State of a source of information regarding GM foods, to which the consumer may resort for information not provided on the product label. In the United Kingdom, this should as soon as possible fall under the remit of the proposed Food Standards Agency (paragraph 140).

### Regulation

193. It is highly desirable that there should be competition between a sufficient number of agro-chemical/seed companies on a world-wide basis. We consider that consolidation should not progress any further (paragraph 85).

194. Provided that the farmer can afford any extra costs, we do not consider either the licensing of the right to plant or the sale of seeds which will produce sterile crops to be a problematic development (paragraph 86).

195. The regulatory process should only judge products on safety: ethical questions should be addressed before regulation, not during or after. In the same way as agreeing the principles for risk assessment, the Council of Ministers will need to agree on how to deal with potentially ethically sensitive modifications such as the inclusion of animal or fish genes in crops. The market might be a suitable arbiter. For some people the use of GM products to any extent is an ethical issue (paragraphs 126–127).

196. The destruction of trials of GM crops by certain groups fundamentally opposed to the technology must be condemned, but increasing confidentiality is not the answer. The advisory committees should continue to place as much information as possible in the public domain. We

welcome the Commission's proposal to do the same at Community level. We agree that public comment should be taken into account formally before ACRE makes its recommendation, rather than informally as at present. Transparency, however, must not affect the efficient working of the regulatory committees (paragraphs 123–125).

197. We do not question ACRE's integrity, but it and its members must be seen to be acting independently. The remit of ACRE should be adjusted so that it considers, for example, indirect and cumulative environmental effects when judging individual applications (paragraphs 148–150).

198. We believe that a new committee, similar to that proposed by the Royal Society, is needed to examine more general issues which arise from the use of genetic modification in agriculture and to co-ordinate and plan policy as a seamless whole (paragraphs 151–153).

199. Domestic pressures, ecological and agricultural conditions vary across the Community. We consider that Member States should have the right to opt-out of growing certain GM crops for domestic or environmental reasons. The products of such crops, food or other, should however be available throughout the Community and the market will determine their acceptability and so success or failure (paragraph 160).

200. We consider that consultation of the Commission's scientific committees will be useful for resolving inter-Member State disputes. The appointment, membership and operation of the committees must be open to scrutiny. The current method of appointment is inadequate. The structure of the committees could also be streamlined to increase their relevance to the regulation of GM releases. The committees require improved resources in Brussels (paragraphs 163–164).

201. We welcome the introduction of strict time limits and the definition of risk assessment which should help end discrepancies between Member States and provide the predictable system desired by industry. There are however two flaws. The first is too ready a willingness to stop the clock. We consider that the efficiency of the scientific committees' working should be improved before resorting to stopping the clock. If this proves impossible, consideration will need to be given as to whether it would be preferable to make the committees permanent or to stop the clock. Additionally, the Commission has failed to set itself a time limit for approving or rejecting a release following the (in)decision of the Council (paragraphs 165–168).

202. We find no merit in the proposal to limit marketing consents to seven year periods (paragraph 170).

203. GMOs need to be regulated, at least until our knowledge develops further, but it would be extremely damaging if Europe's access to this technology was subjected to inappropriate impediments (paragraph 171).

RECOMMENDATION

204. The Committee considers that the proposed revisions to the EC regulation of genetic modification in agriculture raise important questions to which the attention of the House should be drawn, and makes this report to the House for debate.

## APPENDIX 1

*Sub-Committee D (Agriculture, Fisheries and Food)*

The members of the Sub-Committee which conducted this inquiry were:

L. Gallacher
L. Gisborough
L. Grantchester
L. Jopling
L. Moran
L. Rathcavan
L. Reay (Chairman)
L. Redesdale
B. Robson of Kiddington
L. Wade of Chorlton
L. Willoughby de Broke
B. Young of Old Scone

Baroness Wilcox, a member of Sub-Committee C (Environment, Public Health and Consumer Protection), also contributed to this inquiry and report.

The Sub-Committee had as its Specialist Adviser Dr Julian Kinderlerer, Assistant Director, Sheffield Institute of Biotechnological Law and Ethics, Department of Molecular Biology and Biotechnology, University of Sheffield.

Members of the Sub-Committee declared the following interests in relation to this inquiry:

| | |
|---|---|
| L. Gisborough— | Arable and sheep farmer |
| L. Grantchester— | Dairy farmer; member, National Farmers' Union of England and Wales |
| L. Jopling— | Farmer; member, National Farmers' Union of England and Wales; shareholder in Zeneca |
| L. Moran— | Lady Moran is a hill farmer (pedigree cattle) |
| L. Rathcavan— | Hill farmer |
| L. Reay— | Farmer, predominantly grassland |
| L. Redesdale— | Owner of two hill farms |
| L. Wade of Chorlton— | Farmer (William Wild (Mollington) Ltd); director, Murray Vernon Holdings Ltd, traders in milk, fish and meat products |
| L. Willoughby de Broke— | Arable and grassland farmer; chairman, St Martin's Magazines, publishers of *Country Illustrated*; member, National Farmers' Union of England and Wales |
| B. Young of Old Scone— | Chairman, English Nature; member, advisory panel to the Minister of Agriculture, Fisheries and Food |
| B. Wilcox— | President, National Federation of Consumer Groups; member, Institute of Food Research |

No member of the Sub-Committee currently uses or is involved in testing modern genetically modified crops or animals in agriculture.

## APPENDIX 2

*List of Witnesses*

The following witnesses gave evidence. Those marked * gave oral evidence.

AgrEvo
American Soybean Association
Austrian Embassy
* Professor Janet Bainbridge, Director of the School of Science and Technology, University of Teesside and chairman of the advisory committee on novel foods and processes (ACNFP)
* Professor John Beringer, Dean of Science, University of Bristol and chairman of the advisory committee on releases into the environment (ACRE)
* Professor Derek Burke, former Vice-Chancellor, University of East Anglia and former chairman of the advisory committee on novel foods and processes (ACNFP)
British Society of Plant Breeders Limited
Canadian High Commission
Mr Mark Cantley
* Consumers' Association
Consumers in Europe Group
Co-operative Wholesale Society
Professor John Durant, Professor of Public Understanding of Science, Imperial College, University of London and Assistant Director, National Museum of Science and Industry
EuropaBio
* Food and Drink Federation
GeneWatch
Dr Chris Gliddon, School of Biological Sciences, University of Wales
* Green Alliance
* Greenpeace UK
Professor Barrie Gunter, Department of Journalism Studies, University of Sheffield
Health and Safety Executive
* Her Majesty's Government
Horticulture Research International
Embassy of the Republic of Hungary
* Iceland Group plc
Institute of Arable Crop Research
Institute of Grassland and Environmental Research
* Professor Philip James and Dr Andrew Chesson, Rowett Research Institute, Aberdeen
Embassy of Japan
John Innes Centre
LGC Limited
* Monsanto Services International S.A./N.V.
* National Farmers' Union of England and Wales
National Office of Animal Health Limited
Nestlé UK Limited
Novartis UK Ltd
Organisation for Economic Co-operation and Development
Provision Trade Federation
Royal Netherlands Embassy
Royal Society for the Protection of Birds
J Sainsbury plc
* Safeway Stores plc
Scotch Whisky Association
Soil Association
Spanish Embassy
Statutory Nature Conservation Agencies (English Nature, Scottish Natural Heritage, the Countryside Council for Wales and the Joint Nature Conservation Committee)
Unilever plc
* United Biscuits (UK) Limited
United Nations Industrial Development Organization

* United States Department of Agriculture
* Professor Mark Williamson, Professor Emeritus of Biology, University of York
  Dr René von Schomberg
* Zeneca Agrochemicals and Zeneca Plant Science

The Sub-Committee visited the John Innes Research Institute at Norwich and would like to express its profound gratitude to the staff. The working party on genetic modification of the Nuffield Council on Bioethics assisted the Sub-Committee in its deliberations as did the European Commission.

## APPENDIX 3

*Glossary*

### DIRECTIVES AND REGULATIONS

| | |
|---|---|
| **1139/98** | Labelling of certain foodstuffs produced from genetically modified organisms |
| **2100/94** | Community plant variety rights |
| **258/97** | Novel foods and novel food ingredients |
| **90/219/EEC** | Contained use of genetically modified micro-organisms |
| **90/220/EEC** | Deliberate release into the environment of genetically modified organisms |
| **90/679/EEC** | Protection of workers from risks related to exposure to biological agents at work |
| **98/44/EEC** | Legal protection of biotechnological inventions |

### ACRONYMS

| | |
|---|---|
| **ACRE** | Advisory Committee on Releases into the Environment |
| **ACNFP** | Advisory Committee on Novel Foods and Processes |
| **ACGM** | Advisory Committee on Genetic Modification |
| **APHIS** | Animal and Plant Health Inspection Service (of the United States Department of Agriculture) |
| **CA** | Consumers' Association |
| **CEG** | Consumers in Europe Group |
| **COSHH** | Control of substances hazardous to health |
| **CWS** | Co-operative Wholesale Society |
| **DETR** | Department of the Environment, Transport and the Regions |
| **DNA** | Deoxyribonucleic acid, a large molecule which contains all genetic information in the cell for cellular structure, organisation and function |
| **EC** | European Community |
| **EPA** | (United States) Environmental Protection Agency |
| **FAC** | Food Advisory Committee |
| **FDA** | (United States) Food and Drug Administration |
| **FDF** | Food and Drink Federation |
| **FSA** | Food Standards Agency |
| **GM** | Genetic modification (or manipulation) / genetically modified (or manipulated) |
| **HSC** | Health and Safety Commission |
| **HSE** | Health and Safety Executive |
| **LGC** | A private limited company, formerly the Laboratory of the Government Chemist |
| **MAFF** | Ministry of Agriculture, Fisheries and Food |
| **NFU** | National Farmers' Union of England and Wales |
| **NIH** | (United States) National Institutes of Health |
| **OECD** | Organisation for Economic Co-operation and Development |
| **SI** | *Système International* (the international system of units of measurement); or Statutory Instrument |
| **SNCAs** | Statutory Nature Conservation Agencies: English Nature, Scottish Natural Heritage, Countryside Council for Wales and the Joint Nature Conservation Committee |
| **UNEP** | United Nations Environment Programme |
| **UPOV** | International Convention for the Protection of New Varieties of Plants |
| **US** | United States of America |
| **USDA** | United States Department of Agriculture |

### TECHNICAL TERMS

**Antibiotic**— a substance derived from micro-organisms (e.g. bacteria) that destroys or inhibits the growth of other micro-organisms. Many antibiotics are used as drugs in treating disease

**Antibiotic marker gene**—a gene which expresses a protein that enables the organism carrying the gene to tolerate the antibiotic. A marker gene is a gene with a phenotype that can be selected for in gene transfer experiments

**Back-crossing**—cross of a hybrid plant to either one of its parents

**Base**—the components of the DNA molecule. There are four types of bases known as adenine (A), guanine (G), thymine (T) and cytosine (C). The sequence of bases determines the genetic code

**Biological process**—a process which involves a reaction normally carried out in a living cell or organism

**Biotechnology**—the industrial use of biological processes

**Bt**—*Bacillus thuringiensis* – a harmless soil-living bacterium used as a pesticide as it produces crystalline toxins specific to a range of insects

**Cell**—the smallest structural unit of all living organisms that is able to grow and reproduce independently; a cell is formed of a mass of living material surrounded by a membrane

**Chimera**—an organism in which some of the cells (but not all) contain the inserted DNA

**Code**—the sequence of DNA bases which forms the instructions for a given characteristic or trait

**Commercial release**—a release of a genetically modified organism permitted under section C of Directive 90/220/EEC. Anyone throughout the Community is able to purchase, grow, sell and process the crop

**Competent authority**—the Member State authority responsible for issuing release consents. In the United Kingdom this is the Secretary of State (DETR or territorial), normally advised by ACRE where releases into the environment or marketing are concerned

**Contained use**—where the organism is not released into the environment. This might be in a laboratory, or concern an organism where escape and breeding is virtually impossible

**Construct**—gene sequence made *in vitro* containing the genes which on insertion will express the desired characteristic

**Copy gene**—genetic material incorporating the genetic code for a desirable trait which has been copied from DNA of the donor to the host organism. It is not technically possible to take a gene from a donor organism and insert it directly into the host organism

**Crosses**—breeding from different parental varieties

**Cultivar**—a plant variety

**Deliberate release**—Defined by Directive 90/220/EEC as "any intentional introduction into the environment of a GMO ... without provisions for containment such as physical [and/or] chemical ... or biological barriers used to limit their contact with the general population and the environment". Crops are thus released when planted outside

**Double helix**—the physical structure of DNA, consisting of two parallel strands of DNA coiled helically so that the two strands are complimentary

**Enzyme**—a protein produced by living cells that regulates the speed of the chemical reactions involved in the metabolism of living organisms, without itself being altered in the process; also called a biological catalyst

**Expression**—manifestation of the genetic material of the organism

**Feral population**—a plant which successfully invades a new habitat

**Gene**—the biological unit of inheritance; a segment of DNA which provides the genetic information necessary to make one protein

**Gene gun**—a method of introducing genes into cells by firing at high velocity gold particles to which DNA is adsorbed into the cells

**Genetic modification**—a technique where individual genes can be copied and transferred to another living organism to alter its genetic makeup and thus incorporate or delete specific characteristics into or from the organism. The technology is also referred to as genetic engineering, genetic manipulation and gene technology

**Genetically modified organism**—an organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination

**Gene product**—a protein which is formed on expression of a gene

**Gene stacking**—the formation of an organism containing a number of genes all of which are the result of different genetic modifications

**Hazard**—the situation that in particular circumstances could lead to harm

**Herbicide**—a substance toxic to plants used to destroy unwanted vegetation

**Herbicide tolerance**—(in the context of genetic modification) herbicide tolerance introduced by the insertion of a gene or genes capable producing a gene product which inhibits or changes the effect of a herbicide on the plant

**Hybrid** —line of plants produced from a cross between genetically dissimilar parents

**Identity preservation**—a system for securing supplies of unmodified crops for the food industry. It involves ordering the crop in advance and "protecting" it until it reaches the food manufacturer's factory

***In vitro***—(of biological processes) taking place in a test tube or other laboratory equipment

**Molecule**—the smallest fundamental unit (usually a group of atoms) of a chemical compound that can take part in a chemical reaction

**Novel food**—a food which has not been used to a significant degree within the European Community and which falls under one of a number of categories defined in Regulation 258/97

**Pathogenic**—capable of causing disease symptoms

**Pest resistance**—(in the context of genetic modification) pest resistance introduced by the insertion of a gene or genes capable of pest resistance

**Phenotype**—observable characteristic of an organism, for example red flowers (whereas genotype—attributable to the genes)

**Promoter**—the part of a DNA sequence recognised as the signal for the start of a gene.

**Product legislation**—vertical as opposed to horizontal legislation, in this context for foods or feeds as opposed to the technique of genetic modification

**Prokaryote**—an organism which does not have a defined nucleus nor other cell organelles, for example all bacteria

**Protein**—any of a very large group of organic compounds composed of one or more chains of amino-acids and forming an essential part of all living organisms

**Recombinant DNA**—DNA that has been recombined using constituents from different sources

**Recombinant DNA technology**—the deliberate insertion of genes into a DNA molecule using the techniques of modern molecular biology

**Recombination**—the rearrangement, especially by crossing over in chromosomes, of nucleic acid molecules forming a new sequence of the constituent nucleotides

**Refuge**—an area of susceptible crop planted alongside the GMHT or GMPR crop which provides a safe haven for weeds or (more usually) insects where they are not subjected to competitive pressures to evolve resistance

**Risk**— the probability that a particular adverse effect occurs within a stated period of time or results from a particular challenge

**Segregation**—the physical separation of GM crops from unmodified crops in the field, at harvest and thereafter

**Traceability**—a system of record keeping capable of tracing the lineage of the crop to source

**Trial release**—a release of a genetically modified organism permitted under section B of Directive 90/220/EEC. This is an outdoors experiment conducted for research purposes

**Transgene**— inserted genes are termed "transgenes" to differentiate them from indigenous genes

**Volunteer**—plants which survive into the following growing season and which might then become a weed problem in a different crop planted for that season

**Weed**—a plant growing where it is not wanted

**Zoning**—separation of crops on a geographical, climatological or regional basis

## APPENDIX 4

*Table 1: GM crops approved and awaiting approval for commercial release in the EC*

*Updated 28 October 1998—Italics indicate consent issued*

| Date submitted | Competent authority | Notifier | Reference | Description of GMO | Scope of application | Date of consent |
|---|---|---|---|---|---|---|
| *22 June 1992* | *Germany* | *Vemie Veterinar Chemie GmbH* | *C/D/92/1-1* | *Pseudorabies virus strain* | *Immunisation of pigs against Aujeszky's disease* | *18 December 1992* |
| *29 March 1993* | *Belgium* | *Rhone Merienx Belgium* | *C/B/92/1128* | *Rabies vaccine* | *Live vaccine intended for bait for fox consumption* | *20 June 1993* |
| *11 October 1993* | *Germany* | *Vemie veterinar Chemie GmbH* | *C/D93/1–2* | *Pseudorabies virus strain* | *Immunisation of pigs against Aujeszky's disease* | *20 April 1993* |
| 23 Nov 1993 | France | Societe National d'Exploitation des Tabacs et Allumettes | C/F/93/08–02 | Tobacco modified for resistance to oxynil herbicides | Use in agriculture and tobacco industry | Commission adopted decision 8 June 1994 |
| *7 February 1994* | *UK* | *Plant Genetic Systems NV* | *94/M1/1* | *Oilseed rape hybrid system with herbicide tolerance* | *Seed production only* | *28 February 1996* |
| *6 December 1994* | *UK* | *Monsanto Europe* | *94/M3/1* | *Soyabeans modified for tolerance to glyphosafe herbicides* | *Importation, storage and use for animal feeds and food. Not for cultivation* | *7 May 1996* |
| *31 March 1995* | *France* | *Ciba-Geigy* | *C/F/4/11–3* | *Maize modified for insect resistance and herbicide tolerance* | *Use in agriculture in EC and importation of grain into the EC* | *5 February 1997* |
| *27 April 1995* | *Netherlands* | *Bejo Zaden BV* | *C/NL/94/25* | *Red Hearted Chicory modified for altered fertility* | *Seed production only* | *5 August 1996* |
| 27 July 1995 | France | Plant Genetic Systems NV | C/F/95/05–01 (A) | Oilseed rape hybrid system with herbicide tolerance | Importation of seeds for extraction of oil, and agriculture use in EC | Qualified majority vote in favour (5 December 1996) Consent not yet issued |
| 27 July 1995 | France | Plant Genetic Systems NV | C/F/95/05–01 (B) | Oilseed rape hybrid system with herbicide tolerance | Importation of seeds for extraction of oil, and agricultural use in EC | Qualified majority vote in favour (5 December 1996) Consent not yet issued |
| *6 March 1996* | *UK* | *AgrEvo UK Crop Protection* | *C/GB/95/M5/1* | *Oilseed rape modified for tolerance to glufosinate ammonium herbicide* | *Importation of grain for food animal for food, animal feed and industrial uses* | *9 June 1998* |
| 12 March 1996 | France | Pioneer Hi-Bred International | C/F/95/12–01/B | Maize modified for insect resistance and herbicide tolerance | Growing, import, storage and processing of grain and maize products for use in food, feed and industrial products | Vote taken in Regulatory Committee. Outcome unknown |
| 31 May 1996 | France | AgrEvo France | C/F/95/12/07 | Maize modified for tolerance to glufosinate ammonium herbicide | Agricultural use leading to animal and human consumption | Commission adopted decision 22 April 1998. Consent believed to be issued, but not confirmed |
| *3 June 1996* | *UK* | *Northrup King Company* | *C/GB/96/M4/1* | *Maize modified for insect resistance and herbicide tolerance* | *Importation of grain only* | *9 June 1998* |
| 12 June 1996 | France | Monsanto Europe | C/F/12/02 | Maize modified for insect resistance | Production of maize in the EC and import, storage and processing for use in feed, food and industrial products | Commission adopted decision 22 April 1998. Consent believed to be issued, but not confirmed |
| *5 July 1996* | *Finland* | *Valio Ltd* | *C/F1/96/INA* | *Sreptacoccus thermophilus modified as a test kit for the detection of antibiotic residues in milk* | *Use of the kit in dairy industry* | *21 August 1997* |
| 15 July 1996 | Germany | Hoechst Schering AgrEvo GmbH | C/DE/96/5 | Oilseed rape modified for tolerance to glufosinate ammonium herbicide | Same purposes as conventionally bred varieties in EC | Vote not yet taken by Commission |
| 5 August 1996 | Netherlands | AVEBE | C/NL/96/10 | Potatoes modified for altered starch production | Growing, multiplication of breeding material, and processing starch for human consumption | Vote not yet taken by Commission |
| 20 Sept 1996 | Netherlands | Bejo Zaden BV | C/NL/94/25–A | Red Hearted Chicory modified for altered sterility and tolerance to glufosinate ammonium herbicide | Production of vegetable chicory crops | Vote not yet taken by Commission |

| Date submitted | Competent authority | Notifier | Reference | Description of GMO | Scope of application | Date of consent |
|---|---|---|---|---|---|---|
| *25 Sept 1996* | *Netherlands* | *Florigene Europe BV* | *C/NL/96/14* | *Carnation with modified flower colour* | *Cut flowers for purchase by consumers* | *1 December 1997* |
| 29 January 1997 | Belgium | Plant Genetic Systems | C/BE/96/01 | Oilseed rape hybrid system modified for herbicide tolerance | Growing and multiplication for breeding material, feed, food, and industrial uses | Vote not yet taken by Commission |
| 24 October 1997 | Denmark | LF Trifolium A/S Monsanto Europe SA Danisco Seed | C/DK/97/01 | Fodder beet modified for tolerance to glyphostate herbicides | Production of fodder beet in EC | Vote not yet by Commission |
| 15 Dec 1997 | UK | Monsanto Europe | C/GB/97/M3/2 | Maize modified for tolerance to glyphosate herbicides | Importation for processing for use as animal feed and food ingredients. Not be used for cultivation | Application not yet forwarded to the Commission |
| 17 Dec 1997 | Spain | Monsanto Europe | C/ES/97/01 | Cotton modified for tolerance to glyphosate herbicides | The same purposes as non-GM commercial cotton varieties | Vote not yet taken by Commission |
| 17 Dec 1997 | Spain | Zeneca Plant Science | C/ES/96/01 | Tomatoes modified for delayed ripening | Manufacture into food products | Vote not yet taken by Commission |
| 17 Dec 1997 | Spain | Monsanto Europe | C/ES/96/02 | Cotton modified for insect resistance | The same purposes as non-GM commercial cotton varieties | Vote not yet taken by Commission |
| 23 June 1998 | Netherlands | Dekalb Genetics Corporation | C/NL/97/17 | Maize modified for resistance to European corn borer and for tolerance to glufosinate-ammonium herbicides | The same purposes as non–GM maze grain and processed maize products | Vote not yet taken by Commission |
| 30 June 1998 | Sweden | Amylogene HB | C/SE/96/3501 | Potatoes modified for altered starch production | For production of seed potatoes and raw material for the starch industry | Vote not yet taken by Commission |
| *14 August 1998* | *Netherlands* | *Florigene Europe BV* | *C/NL/97/12* | *Carnations modified for increased vaselife* | *For production of cut flowers and horticulture* | *20 October 1998* |
| *14 August 1998* | *Netherlands* | *Florigen Europe BV* | *C/NL/97/13* | *Carnations modified for altered flower colour* | *For production of cut flowers and horticulture* | *20 October 1998* |

*Source:* Biotechnology Unit, CB Division, Department of the Environment, Transport and the Regions.
(For GM crops awaiting approval in the United States, see the Appendix to the USDA's supplementary memorandum, pp. 175-81.)

*Table 2: development of the commercial use of GM crops in the US and EC*

*United States:*

| Crop | 1995 | | 1996 | | 1997 | | 1998 | |
|---|---|---|---|---|---|---|---|---|
| | Total acreage (million acres) | Of which GM (percentage of total) | Total acreage (million acres) | Of which GM (percentage of total) | Total acreage (million acres) | Of which GM (percentage of total) | Total acreage (million acres) | Of which GM (percentage of total) |
| Soya | 61.6 | 0.0 | 63.4 | 1.6 | 69.6 | 12.8 | 71.6 | 35.2 |
| Maize | 65.0 | 0.0 | 73.1 | 1.0 | 73.7 | 9.4 | 73.8 | 27.0 |
| Wheat | 60.9 | 0.0 | 62.9 | 0.0 | 63.6 | 0.0 | 59.1 | 0.0 |
| Other * | 19.0 | <0.1 | 15.8 | 12.0 | 16.5 | 25.4 | 13.9 | ? |

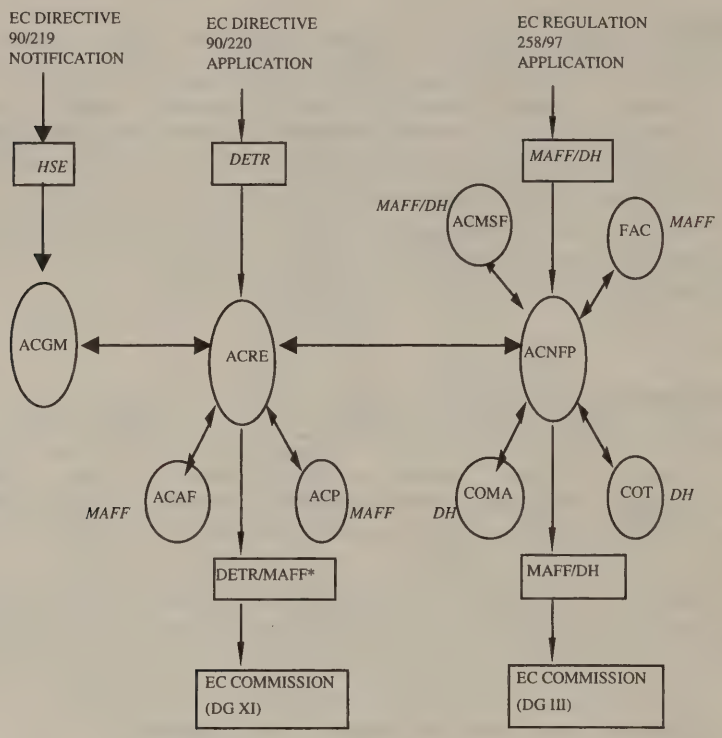
*European Community:*

| Crop | 1995 | | 1996 | | 1997 | | 1998 | |
|---|---|---|---|---|---|---|---|---|
| | Total acreage (million acres) | Of which GM (percentage of total) | Total acreage (million acres) | Of which GM (percentage of total) | Total acreage (million acres) | Of which GM (percentage of total) | Total acreage (million acres) | Of which GM (percentage of total) |
| Soya | 0.8 | 0.0 | 0.8 | 0.0 | 1.0 | 0.0 | 1.1 | 0.0 |
| Maize | 9.5 | 0.0 | 10.4 | 0.0 | 10.8 | 0.0 | 10.3 | 0.1 |
| Wheat | 41.0 | 0.0 | 41.9 | 0.0 | 42.7 | 0.0 | 42.4 | 0.0 |
| Other * | 12.7 | 0.0 | 12.5 | 0.0 | 12.6 | 0.0 | 13.3 | 0.0 |

* Other comprises Cotton, Canola/OSR, Potato, Tomato, Tobacco.

*Source: FAO and ISAAA estimates*

*Figure 1: current structure of the advisory committees in the United Kingdom*




*Sponsoring Department in italics.*

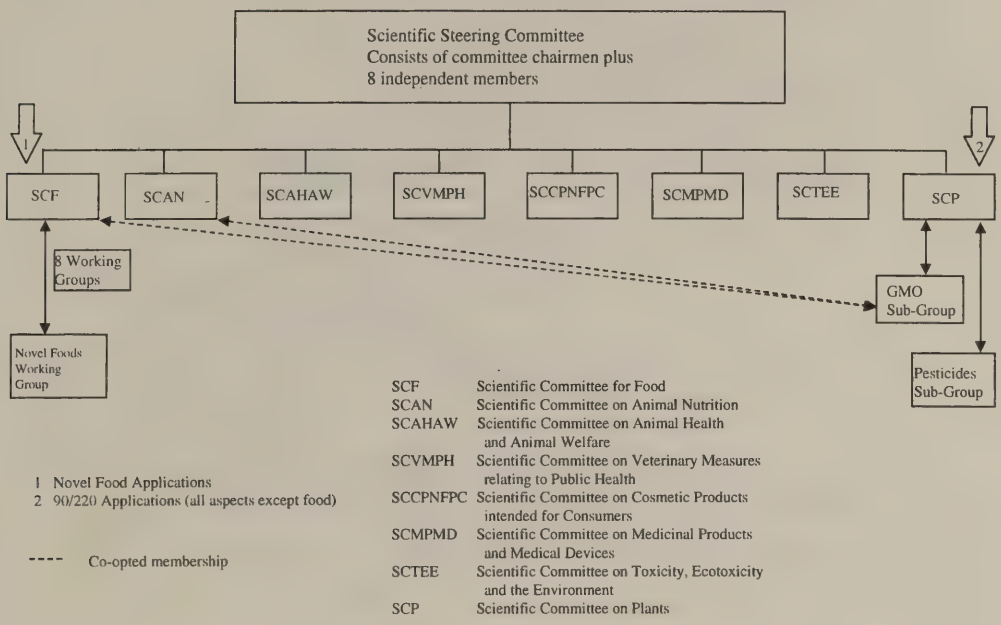
There is cross membership between all Advisory Committees except ACRE/ACP and ACGM/ACNFP where the link is through Departmental officials.

* Where appropriate DETR/MAFF acts together with the Secretaries of State for Scotland, Wales and Northern Ireland.

| | |
|---|---|
| MAFF | Ministry of Agriculture, Fisheries and Food |
| DH | Department of Health |
| ACNFP | Advisory Committee on Novel Foods and Processes |
| FAC | Food Advisory Committee |
| ACRE | Advisory Committee on Releases to the Environment |
| COT | Committee on Toxicity |
| COMA | Committee on Medical Aspects of Food Policy |
| ACP | Advisory Committee on Pesticides |
| ACGM | Advisory Committee on Genetic Modification |
| (ACAF) | Proposed Advisory Committee on Animal feedingstuffs |
| HSE | Health and Safety Executive |
| DETR | Department of the Environment Transport and the Regions |
| ACMSF | Advisory Committee on Microbiological Safety of Food |

Source: Ministry of Agriculture, Fisheries and Food.

*Figure 2: current structure of the European Commission's scientific advisory committees (Directorate-General XXIV)*




Source: Ministry of Agriculture, Fisheries and Food.

*Figure 3: stages of the approval process for commercial release under the current deliberate release Directive (90/220/EEC)*

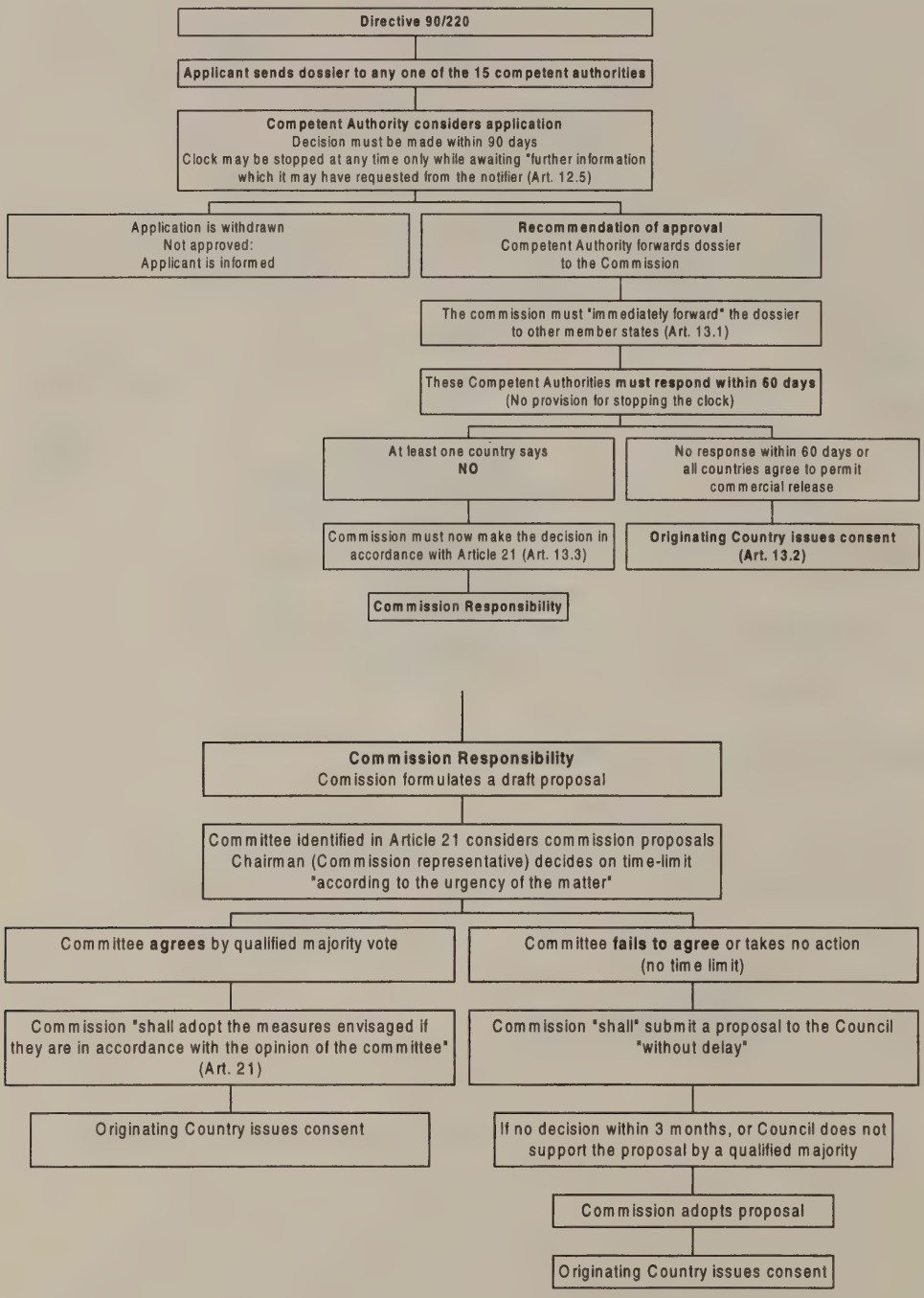
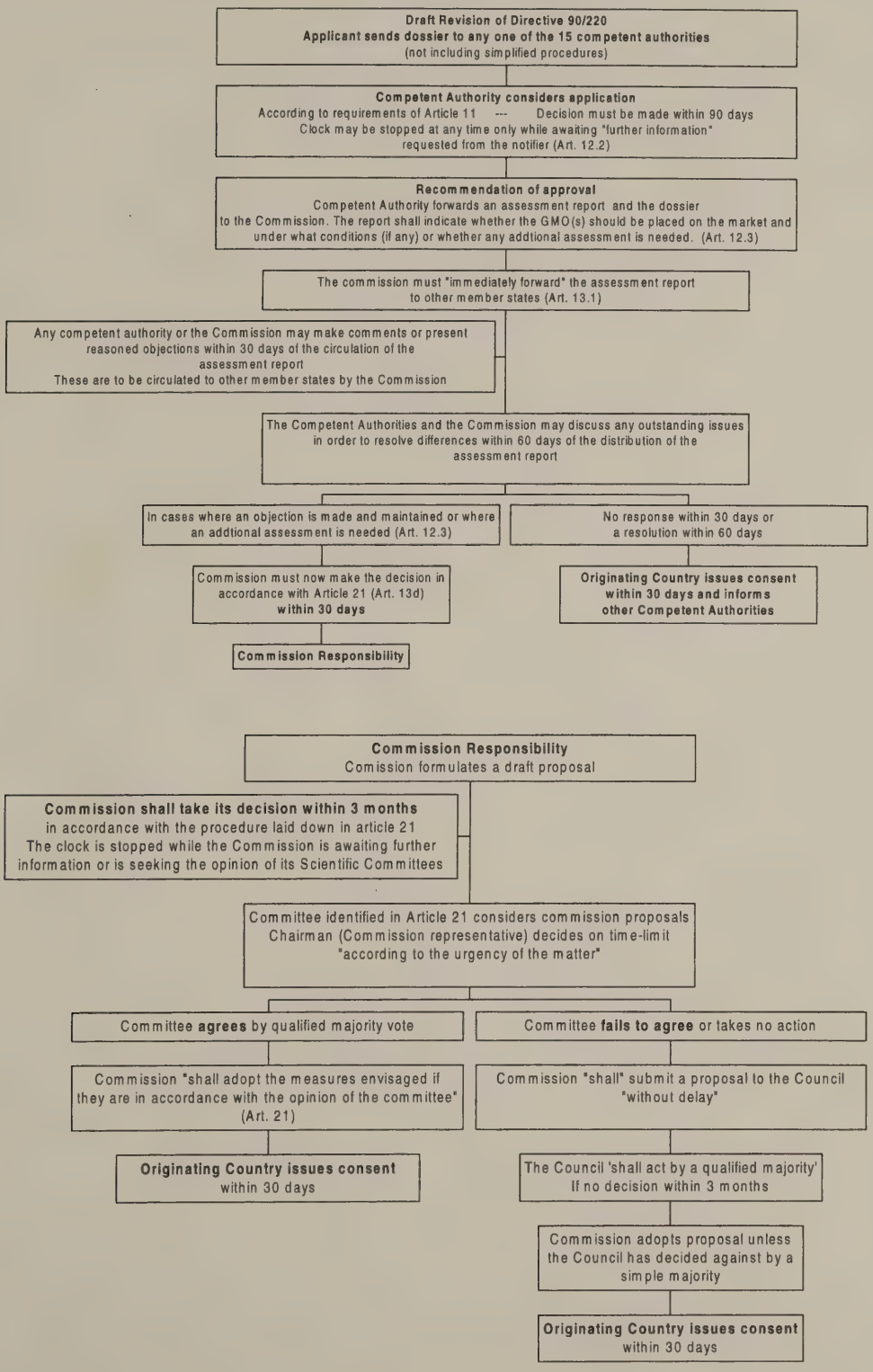


*Figure 4: stages of the approval process for commercial release under the European Commission's proposed revision of the deliberate release Directive*

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